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OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 870

RIN 3206–AM67

Federal Employees' Group Life Insurance Program: Court Orders Prior to July 22, 1998

AGENCY: U.S. Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The Office of Personnel Management (OPM) is issuing this final regulation to adopt as final the interim final regulation published on December 4, 2012. The regulation implements section 8705 of title 5, United States Code regarding the effect of any court decree of divorce, annulment, or legal separation, or any court-approved property settlement agreement incident to any court decree of divorce, annulment, or legal separation (hereinafter "court order") where the court order expressly provides that an individual receive Federal Employee's Group Life Insurance (FEGLI) benefits. The regulations will allow court orders submitted to the appropriate Federal agency before July 22, 1998 to be effective for providing FEGLI benefits if the court order was received in the appropriate office before the insured Federal employee's or annuitant's death. This revision does not affect the current statutory limitation that court orders apply only when FEGLI benefits are based on insured individuals who died on or after July 22, 1998.

DATES: This rule is effective April 27, 2016.

FOR FURTHER INFORMATION CONTACT: Marguerite Martel, Senior Policy Analyst, at (202) 606–0004 or email: *marguerite.martel@opm.gov.*

SUPPLEMENTARY INFORMATION: Public Law 105–205, 112 Stat. 683, enacted July 22, 1998, amending section 8705 of title 5, United States Code, required benefits to be paid in accordance with the terms of a court order instead of the otherwise existing statutory order of precedence for payment of benefits under FEGLI. On October 8, 1999, OPM published a final regulation interpreting the law to mean that only those court orders received in the appropriate office after the date the law was enacted would be valid to name a FEGLI beneficiary. The regulation amended section 870.801(d)(2), of title 5, Code of Federal Regulations.

Based on *Pascavage* v. *Office of Personnel Management,* 773 F. Supp.2d 452 (D. Del. 2011), OPM is changing this regulation to provide FEGLI benefits based on court orders submitted to the appropriate Federal agency before July 22, 1998, so long as the court order was received in the appropriate office before the insured Federal employee's or annuitant's death. This change is consistent with the settlement agreement in this case, *Pascavage* v. *Office of Personnel Management,* C.A. No.: 09–276–LPS–MPT (D. Del. filed Aug. 6, 2012).[1] This revision does not affect the current statutory limitation that court orders apply only when FEGLI benefits are based on insured individuals who died on or after July 22, 1998. On December 4, 2012, OPM published an interim final regulation at 77 FR 71687. We received no comments on the interim final regulation. Therefore, OPM is adopting the interim final regulation with no changes.

Regulatory Impact Analysis

OPM has examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and Executive Order 13563, which directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public, health, and safety effects, distributive impacts, and equity). A regulatory impact analysis must be prepared for major rules with economically significant effects of $100 million or more in any one year. This rule is not considered a major rule because OPM estimates there are relatively few court orders received by the appropriate office before July 22, 1998.

Paperwork Reduction Act

This document does not contain proposed information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13.

Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities because they will apply only to Federal employees, annuitants and their former spouses.

List of Subjects in 5 CFR Part 870

Administrative practice and procedure, Government employees, Hostages, Iraq, Kuwait, Lebanon, Life insurance, Retirement.

U.S. Office of Personnel Management.

Beth F. Cobert,
Acting Director.

PART 870—FEDERAL EMPLOYEES' GROUP LIFE INSURANCE PROGRAM

■ Accordingly, the interim rule amending 5 CFR part 870 which was published at 77 FR 71687 on Dceemmber 4, 2012, is adopted as a final rule without change.

[FR Doc. 2016–09674 Filed 4–26–16; 8:45 am]

BILLING CODE 6325–63–P

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[1] The settlement agreement has been preliminarily approved by the Court.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2010–1167]

Airworthiness Directives Legal Interpretation

AGENCY: Federal Aviation Administration, DOT.

ACTION: Airworthiness directives legal interpretation.

SUMMARY: The Federal Aviation Administration is issuing a legal interpretation on regulations applicable to airworthiness directives. This legal interpretation responds to questions asked by an Aviation Rulemaking Committee and is intended to resolve certain issues for the public.

DATES: April 27, 2016.

FOR FURTHER INFORMATION CONTACT: Douglas Anderson, Manager of Aircraft Certification and Space Law Branch, Office of the Chief Counsel, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: 202–267–3073.

SUPPLEMENTARY INFORMATION:

The Request

This legal interpretation addresses several regulations in Title 14 of the Code of Federal Regulation (14 CFR) part 39 applicable to airworthiness directives. It responds to questions asked by the Federal Aviation Administration's (FAA) Organization/Procedures Working Group of the Airworthiness Directive Implementation Aviation Rulemaking Committee (AD ARC). The Working Group (WG) requested the agency to interpret several provisions in part 39 to resolve issues that have been debated within the WG. These issues partly result from amendments made to part 39 in 2002. *See Airworthiness Directives,* 67 FR 47998 (Jul. 22, 2002). The WG asked four questions:

1. What is the extent of an aircraft operator's continuing obligation following the issuance of an airworthiness directive (AD)?
2. What is the extent of an aircraft operator's obligation to accomplish actions referenced in an AD beyond those actions necessary to resolve the unsafe condition specifically identified in an AD?
3. What is the meaning of the term "applicable" in AD 2007–07–02?
4. What is the extent of an aircraft operator's responsibilities when an AD requires an action that cannot be accomplished on a particular aircraft?

The FAA published for public comment a proposed legal interpretation answering these questions. *Proposed Airworthiness Directive Legal Interpretation,* 76 FR 20898 (Apr. 14, 2011) (Proposed Legal Interpretation).[1] The FAA received numerous comments expressing concern with the FAA's proposed interpretation. Most comments focus on the FAA's responses to questions 1 and 4.

As an initial matter, it is important to emphasize that each AD is unique, and its terms control. Thus, this legal interpretation only addresses the matters raised by the AD ARC and is limited to an interpretation of part 39 and general agency policy governing ADs.

Legal Interpretation, Summary of Comments and the FAA's Responses

Some of the commenters suggested that this interpretation should change the existing part 39 regulations or FAA internal procedures with respect to how ADs are prepared and issued. The FAA rejects those suggestions because a regulation cannot be changed by a legal interpretation; rulemaking is the proper method for amending a regulation.

Some of the comments raised policy considerations, which provide valuable information to the FAA, but those policy considerations cannot change the present wording of the regulations, and are best taken into account during rulemaking. A legal interpretation only may explain the meaning of the words that are in the existing regulation; it may not create new policy. Set forth below is a summary and response to comments as to the proper interpretation of existing provisions of part 39.

Question 1: What is the extent of an aircraft operator's continuing obligation following the issuance of an airworthiness directive (AD)?

Answer: The FAA interprets §§ 39.7 and 39.9 to mean that operators have an ongoing obligation to ensure that the modification mandated by an AD is maintained.

For changes to AD-mandated modifications and for deviations from ADs that do not have a terminating action, the operator must obtain approval for an alternative means of compliance (AMOC) with the AD. The FAA recognizes that in some cases this may impose a burden on operators to obtain AMOC approvals for activities that would otherwise be considered normal maintenance. The FAA may allow, on an AD-by-AD basis, reversion to part 43 maintenance, with airworthiness limitations if appropriate to prevent operators from reintroducing unsafe conditions.

Summary of Comments Received

Some commenters contended that the words of the regulation must be given their plain meaning and that the proposed interpretation is not consistent with the regulatory text. Section 39.9 provides, "If the requirements of an airworthiness directive have not been met, you violate § 39.7 each time you operate the aircraft or use the product." Some commenters suggested that this means that once the requirements of the AD are met, the action has been taken to resolve the unsafe condition and the AD is, therefore, no longer applicable. Indeed, some commenters further contended that after the AD's requirements have been met, it is likely that the product will be in a new type design that is different from the type design covered under the AD, and therefore, the product now falls out of the AD's applicability. While some commenters contended that § 39.9 contains no continuing obligation to maintain an AD-mandated condition, other commenters suggested that the standard maintenance practices under other parts should then control. A significant number of the comments objected to maintaining an AD-mandated configuration in perpetuity without any allowance for or consideration of normal maintenance, alterations, and design changes properly performed and approved in accordance with parts 21 and 43.

FAA's Response to Comments

Under §§ 39.7 and 39.9, operators must comply with the requirements of applicable ADs and must operate aircraft in accordance with all applicable ADs. Section 39.7 prohibits the operation of a product that fails to meet AD requirements. Section 39.9 imposes a continuing obligation to maintain compliance with an AD by establishing a separate violation for each time an aircraft is operated or a product is used that fails to meet AD requirements. When these sections are read together in the context of part 39, an AD requires that products be operated free of any identified unsafe condition. The FAA issues ADs not only to require operators to accomplish particular actions listed in the AD, but also to ensure that, when products are operated, they are free of identified unsafe conditions. It is important that once the unsafe condition is corrected as required by an AD, the unsafe condition not be reintroduced. Even if the configuration of the airplane has changed to comply with the AD, it does not mean that the AD no longer applies.

There are two main categories of ADs issued by the FAA: (1) Ongoing inspection and/or maintenance requirements that address a known unsafe condition or an unsafe condition likely to exist; and (2) ADs that require modifications, which may be "terminating actions" for ongoing requirements, and which remove the unsafe condition. Sections 39.7 and 39.9 impose a continuing obligation to comply with both types of AD requirements.

The comments appear to manifest confusion regarding the second type of AD and specifically the use of the term "terminating action" in an AD. While how that term is used in an individual AD controls, general guidance of the FAA's general use of such term follows. Terminating action ADs allow or direct operators to perform a maintenance action that removes the unsafe condition from the affected aircraft and eliminates the need for the AD's inspection requirements. One example of a terminating action is the removal and replacement of a defective part that had been subject to AD-mandated repetitive inspections. After a "terminating action," the resulting configuration constitutes an FAA-approved type design which must be maintained as required by §§ 39.7 and 39.9. This configuration must also be maintained in order for the aircraft to be airworthy.[2]

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[1] In response to several requests, the FAA extended the comment period until June 30, 2011. 76 FR 30040 (May 24, 2011).

Terminating actions fall into two broad categories—those that either (1) correct whatever defect kept the product from conforming to an approved type design; or (2) accomplish a required change in type design where the FAA has determined that the original type design does not comply with the applicable airworthiness standards. In both cases, the post-AD configuration meets type certification requirements and renders the aircraft in a condition for safe operation. An aircraft operator must maintain that resulting configuration, and may not change it to any other configuration that does not comply either with the AD or with an approved AMOC to the AD.

For ADs mandating modifications where the AD requires no further action after modification, the operator may perform standard maintenance practices on that new configuration, associated with maintaining the fleet, which would not change the required modification, and may do so without AMOC approval. Any change from the mandated modification, however, requires FAA approval of an AMOC.[3]

When an unsafe condition is eliminated in production before the FAA issues the AD, the FAA limits the applicability of the AD requirements to exclude those newly produced aircraft. Those new aircraft resolve the unsafe condition by having appropriate modifications incorporated into their type design during production and initial airworthiness certification. Continued compliance with the type design, inspection, and maintenance requirements under parts 21 and 43 for that product should ensure that operators maintain the product's condition for safe operation. In contrast, when the FAA issues an AD, it is because the agency determined that regulatory requirements have not effectively prevented an unsafe condition of the affected products. Therefore, § 39.7 requires that, when a product is operated, it must meet the requirements of all applicable ADs including any ongoing mandated inspection and maintenance requirements that may override general part 43 maintenance practices.

Question 2: What is the extent of an aircraft operator's obligation to accomplish actions referenced in an AD beyond those actions necessary to resolve the unsafe condition specifically identified in an AD?

Answer: An AD may require more actions than correcting the specific unsafe condition. These may include actions reasonably related to resolving or preventing the unsafe condition. Thus, an aircraft operator has an obligation to accomplish all actions required by an AD including those beyond the actions necessary to resolve the unsafe condition specifically identified in an AD.

Summary of Comments Received

Some commenters argued that the FAA's interpretation is not consistent with the regulatory text because by its terms § 39.11 is limited to actions to resolve only the "unsafe condition." According to such commenters, if an action required by the AD does not directly affect the unsafe condition, those actions are over-prescriptive and outside the scope of the FAA's authority.

Other commenters take the opposite view. As Airbus, a design approval holder (DAH) noted, operators often request complete sets of instructions for preparation, procedures, test, and closing up. Additionally, DAH-determined tools, methods, proceedings, materials, and instructions to be used for accomplishing a service instruction for continued airworthiness are part of the type design under § 21.31.

FAA's Response to Comments

The FAA's interpretation is consistent with Title 49 of United States Code, Section 44701, which establishes the FAA's broad authority to issue regulations in the interest of aviation safety and the FAA issues ADs under such authority. In addition, § 39.11 of the regulations provides:

> § 39.11 *What actions do airworthiness directives require? Airworthiness directives* specify inspections you must carry out, conditions and limitations you must comply with, and any actions you must take to resolve an unsafe condition (emphasis added).

When describing the types of actions required by an AD, which is a final rule, § 39.11 does not limit the agency's broad statutory authority. AD requirements are imposed by the language of the AD itself and not by § 39.11. Thus, an AD may require more actions than simply correcting the specific unsafe condition by, for example, requiring certain continuing maintenance actions to prevent or detect the unsafe condition in the future.

In developing an AD, the FAA determines the range of actions that are reasonably related to and further the interest of aviation safety.[4] For example, service information frequently includes instructions for accessing the area to be worked on to address the unsafe condition. Because these access instructions are reasonably related to addressing the unsafe condition, the FAA has the authority to mandate such instructions by AD.

The rulemaking process by which individual ADs are adopted provides the public with an opportunity to identify and express concern with potentially overly prescriptive requirements. In addition, each AD contains a provision allowing for approval of an AMOC, which allows an operator to address an unsafe condition in a manner approved by the FAA.

Question 3: What is the meaning of the term "applicable" in AD 2007–07–02?[5]

Answer: The FAA interprets "applicable" to limit the required actions to those that apply to a particular aircraft under the specific conditions found. The use of "applicable" does not permit an operator to decide which actions are necessary to correct the unsafe condition.

Summary of Comments Received

One commenter contended there was no ambiguity in the subject AD because the SB specifically list the fleets affected, and which steps are applicable based on several different configurations of various aircraft. Therefore, the commenter concluded there is no need to include the word "applicable" to exclude those products for which the requirements clearly do not apply.

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[2] Any operation of an unairworthy aircraft is subject to enforcement action under Part 91.

[3] Parts 21 and 43 also prohibit the reintroduction of an unsafe condition.

[4] The FAA has "broad authority to require whatever types of corrective actions we determine to be most effective in addressing identified unsafe conditions. This includes inspections, repairs, modifications, operating limitations, airworthiness limitations, and maintenance program requirements." *Airworthiness Directives,* 67 FR 47998–01 (Jul. 22, 2002). The FAA issues ADs under the Administrative Procedure Act (APA); therefore, if the actions required by an AD are reasonably related to resolution of the unsafe condition, the FAA may mandate them. 5 U.S.C.A. § 551 *et seq.*

[5] *AD 2007–07–02* paragraph (f) states in pertinent part that operators must "do[] all the applicable actions specified in the Accomplishment Instructions of the applicable service bulletin specified in Table 1 of this AD.".

ARSA commented that under part 39 the FAA cannot make anything "applicable" that is not directly related to the unsafe condition and specified actions must be limited to those that directly address the unsafe condition. In its view, the FAA's interpretation mandates accomplishing all actions, whether or not necessary to correcting the unsafe condition, which is contrary to part 39.

FAA's Response to Comments

The FAA intends "applicable" to have the same meaning in both places in paragraph (f) of *AD 2007–07–02.* The first usage limits the required actions to those that apply to a particular aircraft under the specific conditions found; it does not permit an operator to decide which actions are necessary and which are unnecessary to correct the unsafe condition.

The second usage references Table 1 in the AD that identifies the model of aircraft to which each service bulletin applies. The "applicable service bulletin" means the service bulletin that applies to each corresponding aircraft model, as indicated in Table 1 of the AD. Similarly, "all the applicable actions" specified in each applicable service bulletin are those actions that are identified as applying to a particular aircraft. "Applicable" is a necessary qualifier in this context for two reasons: (1) In many ADs, the referenced service bulletins specify different actions for different aircraft configurations, typically identified as "Group 1," "Group 2," etc.; (2) in many ADs, the referenced service bulletins specify different actions depending on conditions found during performance of previous steps in the instructions (*e.g.,* if a crack is smaller than a specified size, repair in accordance with the Structural Repair Manual; if larger, repair in accordance with a method approved by the Aircraft Certification Office). The term "applicable" limits the AD's requirements to only those that are specified in the service bulletin for the configuration and conditions of a particular aircraft. In this case, the word "all" means that every applicable action must be accomplished.

Although this response applies specifically to AD 2007–07–02, this general principle also applies to uses of the term "applicable" in other ADs. The FAA promulgates ADs with specific standards to directly address the identified unsafe condition. As exemplified by AD 2007–07–02, ADs often require many different actions for various models and aircraft configurations. Because of those complexities, mandating AD actions without incorporating by reference the manufacturer's service bulletin that may contain "normal" part 43 maintenance actions becomes impracticable or may interject unnecessary complexities or inconsistencies that adversely affect performance of the necessary corrective actions.

Question 4: What is the extent of an aircraft operator's responsibilities when an AD requires an action that cannot be accomplished on a particular aircraft?

Answer: Sections 39.15 and 39.17 require ADs to apply to a specific product, even if the product has been changed through component removal or replacement or other modification. An operator who cannot comply with the specific requirements of an AD must request approval of an AMOC from the FAA. The operator must obtain an AMOC approval even if the affected component has been removed from the aircraft, rendering compliance with the specific requirements of the AD impossible. The AMOC process allows the FAA to determine whether the unsafe condition has been eliminated when an operator removes a component addressed in an AD and replaces it with a different component.

Summary of Comments

Some commenters stated the FAA's interpretation is either wrong because when the AD pertains to a specific part or component that has since been legally removed or pertains to a part or such that is not installed on the aircraft, the AD no longer applies, or represents a change from past practice or guidance.

FAA Response to Comments

If a change to a product makes it impossible to comply with the requirements of an AD, then the operator must request an AMOC approval from the FAA. Sections 39.15 and 39.17 directly answer this issue. Section 39.15 provides that an AD applies to each product identified in the AD, even if an individual product has been changed by modifying, altering, or repairing it in the area addressed by the AD. Section 39.17 requires that if a change in a product affects an operator's ability to accomplish the actions required by the AD in any way, the operator must request FAA approval of an AMOC. Together these sections require an operator who cannot comply with the specific requirements of an AD to request FAA approval of an AMOC. The operator must obtain an AMOC approval even if the affected product has been removed from the aircraft, rendering compliance with the specific requirements of the AD impossible. The AMOC process allows the FAA to determine whether the unsafe condition has been eliminated when an operator removes a component to which an AD applies and replaces it with a different component.

This approach was clearly specified in the FAA's part 39 rulemaking in 2002. *See Airworthiness Directives,* 67 FR 47998 ("Specifically, FAA is adding to part 39 the language explaining that ADs apply even if products have been modified, altered, or repaired in the area addressed by the directive."). The 2002 rulemaking did not introduce any new regulatory requirements; rather, the FAA simply codified in part 39 provisions currently found in ADs. *Id.* at 47999. If a change in a product affects one's ability to comply with the AD, the person operating the aircraft or using the product must ask the FAA's permission to use an AMOC, and the request must either show that the change eliminated the unsafe condition or include the specific actions proposed. *Id.* at 48000.

This response was coordinated with the Aircraft Maintenance Division of the Flight Standards Service and the Design, Manufacturing and Airworthiness Division of the Aircraft Certification Service.

Issued in Washington, DC, on April 19, 2016.

Lorelei Peter,

Assistant Chief Counsel for Regulations.

[FR Doc. 2016–09667 Filed 4–26–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–4474; Directorate Identifier 2015–NE–34–AD; Amendment 39–18485; AD 2016–08–09]

RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney Division Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain

Pratt & Whitney Division (PW) PW4000–94 inch and PW4000–100 inch model turbofan engines. This AD was prompted by a report of a crack found in the high-pressure compressor (HPC) 10th stage disk. This AD requires performing an ultrasonic inspection (USI) or an eddy current inspection (ECI) of the HPC 10th stage disk. We are issuing this AD to prevent failure of the HPC 10th stage disk, uncontained disk release, damage to the engine, and damage to the airplane.

DATES: This AD is effective June 1, 2016.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of June 1, 2016.

ADDRESSES: For service information identified in this final rule, contact Pratt & Whitney Division, 400 Main St., East Hartford, CT 06108; phone: 860 565–8770; fax: 860 565–4503. You may view this service information at the FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call (781) 238–7125. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–4474.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–4474; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Katheryn Malatek, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7747; fax: 781–238–7199; email: *katheryn.malatek@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain PW PW4000–94 inch turbofan engines with HPC 10th stage disk, part number (P/N) 51H710 or 53H976–06, installed and certain PW4000–100 inch turbofan engines with HPC 10th stage disk, P/N 53H976–06, installed. The NPRM published in the **Federal Register** on December 9, 2015 (80 FR 76400). The NPRM was prompted by a report of a crack found in the HPC 10th stage disk. The root cause of the crack was a manual polishing procedure, previously used during manufacture, that caused surface scratches on the disk. The NPRM proposed to require a USI or ECI of the HPC 10th stage disk. We are issuing this AD to prevent failure of the HPC 10th stage disk, which could lead to an uncontained disk release, damage to the engine, and damage to the airplane.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM (80 FR 76400, December 9, 2015) and the FAA's response to each comment.

Support for the NPRM

The Boeing Company and United Airlines expressed support for the NPRM (80 FR 76400, December 9, 2015).

Request To Use ECI as Follow-on to USI

American Airlines requested that we revise Compliance paragraph (e) of this AD to add a statement that the ECI can be used to confirm the presence of a crack if a USI is initially performed and the ECI is the final authority on whether or not a crack is present on the disk.

We agree. We revised Compliance paragraph (e) of this AD to allow a follow-on ECI.

Request To Allow Disk Replacement Repairs

Atlas Air requested that we revise the Compliance paragraph (e) of this AD to allow use of disk replacement repairs per the PW PW4000–94/100 Clean, Inspect, Repair (CIR) Manual Part No. 51A357, Section 72–35–10, Repair 07.

We disagree. This AD requires removal of the 10th stage disk if it fails inspection. There are no FAA-approved repairs allowed on the 10th stage disk. The previously approved PW4000–94/100 CIR Manual Part No. 51A357, Section 72–35–07, Repair 04 to the drum rotor, replaces the disk, resulting in a part eligible for installation. We did not change this AD.

Request To Allow ECI at Overhaul

Air India Limited requested that Compliance paragraph (e) of this AD allow an ECI when the HPC is "overhauled" rather than when it is "removed from the engine." Air India Limited indicated that "overhauled" is clearer than "removed from the engine".

We disagree. The intent of this AD is to inspect the 10th stage disk at exposure. The phrase, "Whenever the HPC front drum rotor is removed from the engine . . ." clearly describes the appropriate level of exposure for performing the ECI. We did not change this AD.

Request To Waive Repeat USI

Air India Limited requested that we revise Compliance paragraph (e) of this AD to indicate that a repeat USI should be waived to reduce the maintenance burden if the low-pressure turbine (LPT) is removed in less than 100 hours since the last USI.

We disagree. Our safety risk assessment assumed that a USI is performed whenever the high-pressure turbine (HPT) or LPT is removed from the engine and an ECI is performed whenever the HPC front drum rotor disk assembly is removed from the engine. We determined the inspection interval in the Compliance paragraph (e) of this AD provides an acceptable level of safety. We did not change this AD.

Request To Remove Compliance Statement

FedEx requested that we revise Compliance paragraph (e) of this AD to remove the statement, "Comply with this AD within the compliance times specified, unless already done." FedEx stated that there are no compliance times specified and the compliance requires a repetitive inspection, so the statement does not apply.

We disagree. The statement ". . . unless already done" allows an operator who has performed an initial inspection before the effective date of the AD, but has not yet returned the part to service, to take credit for that action. While there is no calendar or cyclic time given, the requirements of this AD must be met when the HPT, LPT, or HPC front drum rotor disk assembly is removed from the engine. We did not change this AD.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD with the changes described previously. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (80 FR 76400, December 9, 2015) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already

proposed in the NPRM (80 FR 76400, December 9, 2015).

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Related Service Information Under 1 CFR Part 51

We reviewed PW Alert Service Bulletin (ASB) PW4G–100–A72–255, dated August 31, 2015 and PW ASB PW4ENG A72–833, dated August 20, 2015. The ASBs provide lists of affected HPC disks and describe procedures for USI and ECI of the HPC 10th stage disk. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD affects 763 engines installed on airplanes of U.S. registry. We also estimate that it would take about 12 hours per engine to do the inspection. The average labor rate is $85 per hour. Based on these figures, we estimate the cost of this AD on U.S. operators to be $778,260.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a "significant regulatory action" under Executive Order 12866,

(2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2016–08–09 Pratt & Whitney Division: Amendment 39–18485; FAA–2015–4474; Directorate Identifier 2015–NE–34–AD.

(a) Effective Date

This AD is effective June 1, 2016.

(b) Affected ADs

None.

(c) Applicability

(1) This AD applies to all Pratt & Whitney Division (PW) PW4050, PW4052, PW4056, PW4060, PW4060A, PW4060C, PW4062, PW4062A, PW4152, PW4156, PW4156A, PW4158, PW4160, PW4460, PW4462, and PW4650 turbofan engines, including models with a "-3" suffix, with one of the following installed:

(i) High-pressure compressor (HPC) 10th stage disk, part number (P/N) 51H710, with a serial number (S/N) listed in Table 1 of PW Alert Service Bulletin (ASB) PW4ENG A72–833, dated August 20, 2015; or

(ii) HPC 10th stage disk, P/N 53H976–06, with an S/N listed in Table 2 of PW ASB PW4ENG A72–833, dated August 20, 2015.

(2) This AD also applies to all PW PW4164, PW4168, PW4168A, PW4164C, PW4164C/B, PW4170, PW4168A–1D, PW4168–1D, PW4164–1D, PW4164C–1D, and PW4164C/B–1D turbofan engines with an HPC 10th stage disk, P/N 53H976–06, with an S/N listed Table 1 of PW ASB PW4G–100–A72–255, dated August 31, 2015, installed.

(d) Unsafe Condition

This AD was prompted by a report of a crack found in the HPC 10th stage disk. We are issuing this AD to prevent failure of the HPC 10th stage disk, uncontained disk release, damage to the engine, and damage to the airplane.

(e) Compliance

Comply with this AD within the compliance times specified, unless already done.

(1) After the effective date of this AD, whenever the high-pressure turbine (HPT) or low-pressure turbine (LPT) is removed from the engine, perform an ultrasonic inspection (USI) of the HPC 10th stage disk for cracks. If the HPC 10th stage disk fails the USI, perform a follow-on eddy current inspection (ECI) or remove the disk from service and replace with a part eligible for installation.

(2) After the effective date of this AD, whenever the HPC front drum rotor disk assembly is removed from the engine, perform an ECI of the HPC 10th stage disk for cracks. Remove from service any HPC 10th stage disk that fails inspection and replace with a part eligible for installation. A USI as required by paragraph (e)(1) of this AD is not required if an ECI is performed.

(f) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request. You may email your request to: *ANE-AD-AMOC@faa.gov.*

(g) Related Information

For more information about this AD, contact Katheryn Malatek, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7747; fax: 781–238–7199; email: *katheryn.malatek@faa.gov.*

(h) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Pratt & Whitney (PW) Alert Service Bulletin (ASB) PW4G–100–A72–255, dated August 31, 2015.

(ii) PW ASB PW4ENG A72–833, dated August 20, 2015.

(3) For PW service information identified in this AD, contact Pratt & Whitney Division, 400 Main St., East Hartford, CT 06108; phone: 860–565–8770; fax: 860–565–4503.

(4) You may view this service information at FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call

202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Burlington, Massachusetts, on April 7, 2016.

Colleen M. D'Alessandro,

Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2016–09687 Filed 4–26–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–4344; Directorate Identifier 2015–NE–32–AD; Amendment 39–18486; AD 2016–08–10]

RIN 2120–AA64

Airworthiness Directives; General Electric Company Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all General Electric Company (GE) CF6–80C2A1, CF6–80C2A2, CF6–80C2A3, CF6–80C2A5, CF6–80C2A5F, CF6–80C2A8, CF6–80C2B1, CF6–80C2B1F, CF6–80C2B1F1, CF6–80C2B1F2, CF6–80C2B2, CF6–80C2B2F, CF6–80C2B3F, CF6–80C2B4, CF6–80C2B4F, CF6–80C2B5F, CF6–80C2B6, CF6–80C2B6F, CF6–80C2B6FA, CF6–80C2B7F, CF6–80C2B8F, CF6–80C2D1F, CF6–80C2L1F, CF6–80C2K1F and CF6–80E1A1, CF6–80E1A2, CF6–80E1A3, CF6–80E1A4, and CF6–80E1A4/B turbofan engines. This AD was prompted by reports of a burn-through of the accessory heat shield during an engine fire, propagating the fire into the accessory compartment and igniting additional flammable fuel source. This AD requires replacing the accessory heat shield assembly. We are issuing this AD to prevent fires from propagating into the accessory compartment, resulting in an uncontrolled engine fire, and damage to the airplane.

DATES: This AD is effective June 1, 2016.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of June 1, 2016.

ADDRESSES: For service information identified in this final rule, contact General Electric Company, GE Aviation, Room 285, 1 Neumann Way, Cincinnati, OH 45215; phone: 513–552–3272; email: *aviation.fleetsupport@ge.com.* You may view this service information at the FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–4344.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–4344; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Herman Mak, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7147; fax: 781–238–7199; email: *herman.mak@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to GE CF6–80C2A1, CF6–80C2A2, CF6–80C2A3, CF6–80C2A5, CF6–80C2A5F, CF6–80C2A8, CF6–80C2B1, CF6–80C2B1F, CF6–80C2B1F1, CF6–80C2B1F2, CF6–80C2B2, CF6–80C2B2F, CF6–80C2B3F, CF6–80C2B4, CF6–80C2B4F, CF6–80C2B5F, CF6–80C2B6, CF6–80C2B6F, CF6–80C2B6FA, CF6–80C2B7F, CF6–80C2B8F, CF6–80C2D1F, CF6–80C2L1F, and CF6–80C2K1F turbofan engines. This AD that would also apply to CF6–80E1A1, CF6–80E1A2, CF6–80E1A3, CF6–80E1A4, and CF6–80E1A4/B turbofan engines. The NPRM published in the **Federal Register** on December 7, 2015 (80 FR 75952). The NPRM was prompted by reports of a burn-through of the accessory heat shield during an engine fire leading to an accessory compartment fire. A fire burns through the accessory heat shield and ignites the integrated drive generator (IDG) and main fuel pump, which supports further combustion. The existing accessory heat shield assembly leaves a large area above the sensitive accessories, such as the IDG and the main fuel pump, without adequate protection. A total of three burn-through events have occurred. The NPRM proposed to require replacing the accessory heat shield assembly. We are issuing this AD to prevent an uncontrolled engine fire, and damage to the airplane.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM (80 FR 75952, December 7, 2015) and the FAA's response to each comment.

Support for the NPRM (80 FR 75952, December 7, 2015)

The Boeing Company and the National Transportation Safety Board expressed support for the NPRM (80 FR 75952, December 7, 2015).

Revision to Service Information

We revised the Discussion section and Applicability paragraph (e) of this AD to include all the GE CF6–80C2 and CF6–80E1 turbofan engine models.

Request To Change Summary

GE requested that we revise the Summary paragraph of this AD to correct the number of events and clarify the event description.

We agree. Only three of the originally specified five events resulted in heat shield burn-throughs. We revised the Summary paragraph of this AD to correct the number of events and clarify the event description.

Request To Revise the Other Related Service Information Paragraph

GE requested that we revise the Other Related Service Information paragraph of this AD to remove GE Service Bulletin (SB) CF6–80C2 S/B 72–1523, dated September 22, 2015. This SB only applies to the military variant of the engine.

We disagree. The military variant of the engine is also certified by the FAA. We did not change this AD.

Request To Revise the Costs of Compliance

GE, KLM Royal Dutch Airlines (KLM), All Nippon Airways (ANA), and Federal Express (FedEx) requested that we revise the Costs of Compliance paragraph of this AD to correct the parts cost used in the calculations.

We agree. We considered the costs of all the parts needed to comply with this AD and revised the costs per engine to $14,207 and the total cost to U.S. operators to $13,680,920.

Request To Change Applicability

KLM requested that we exclude GE CF6–80E1 engines from the Applicability paragraph of this AD. KLM reasoned that the NTSB safety recommendation did not address GE CF6–80E1 engines and CF6–80E1 engines have not experienced any sump fires to date.

We disagree. Although the NTSB did not address GE CF6–80E1 engines, the designs of the GE CF6–80C2 and CF6–80E1 engines are substantially similar. Therefore, the unsafe condition addressed by this AD is likely to exist or develop on the GE CF6–80E1 engines. We did not change this AD.

Request To Change Compliance

GE requests that the following part numbers (P/Ns) be removed from Table 1 of GE SB 72–1520: P/N 2022M47G01, P/N 2022M81P01, P/N 2022M85G01, and P/N 2023M20G01. These P/Ns are used only on GE CF6–80C2B6FA models, a military application, and contain a different heat shield design.

We disagree. The specified P/Ns are not listed in Table 1 of GE SB 72–1520 and therefore this comment is not applicable. We did not change this AD.

Request To Change Definition

GE, United Airlines, KLM, Lufthansa, Lufthansa Cargo, Lufthansa Technik, and FedEx requested that we provide a more accurate description of flange separation and exclude certain situations from the definition of a shop visit. The commenters reasoned that this would provide clarity and reduce the undue economic and operational burden of complying with this AD earlier than necessary.

We agree. We revised the Definition paragraph of this AD to clarify the description of flange separation and include specific conditions that do not qualify as shop visits.

Request To Delay the Effective Date

GE and Delta Air Lines (Delta) requested that we delay the effective date of this AD. GE reasoned that the revised service bulletin addressing the lack of repair instructions for accessory heat shield assembly, P/N 1313M94G09, will not be available until after the expected effective date of this AD.

We disagree. The current effective date of this AD is needed to address the unsafe condition for the affected fleet. Any party may make a request for an Alternative Method of Compliance (AMOC) to this AD using the procedures listed in this AD. Any requests for an AMOC are reviewed and responded to accordingly. We did not change this AD.

Request To Change Applicability

ANA requested limiting the Applicability paragraph of this AD to a particular maintenance, repair, and overhaul (MRO) shop where improper maintenance occurred leading to fire. ANA reasoned that the latest 2010 sump fire leading to heat shield burn-through was the result of improper maintenance at a particular MRO.

We disagree. This AD addresses the insufficient fire protection design of the heat shield to prevent secondary fire damage. This is independent from the cause of fire in the engine. We did not change this AD.

Request To Change Effectivity

Lufthansa, Lufthansa Cargo, and Lufthansa Technik requested that we not mandate heat shield rework or replacement. Lufthansa reasoned that none of their customers operating GE CF6–80C2/80A engines have experienced a compressor rear frame (CRF) sump fire.

We disagree. Complying with this AD is necessary to correct the unsafe condition of heat shield burn-through. The heat shield rework or replacement is needed to prevent fires from propagating into the accessory compartment, leading to a larger engine fire and subsequent damage to the airplane. We did not change this AD.

Request for Allowance of Creating and Marking Serial Numbers

Delta requested we allow operators to both create and mark identification numbers on heat shields that are not currently marked. Delta has received reports that there are illegible identification markings on heat shields.

We partially agree. We agree there is a lack of information about heat shields with illegible P/Ns in this AD. We revised the Compliance section of this AD to address heat shields with illegible P/Ns.

We disagree with allowing operators to create and mark identification numbers on heat shields as this does not resolve the unsafe condition and is beyond the scope of this AD.

Request To Change Applicability

GE commented that heat shield, P/N 1643M23G12, is also affected by the unsafe condition described in this AD.

We agree. We added heat shield, P/N 1643M23G12, to the applicability of this AD.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD with the changes described previously. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (80 FR 75952, December 7, 2015) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (80 FR 75952, December 7, 2015).

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Related Service Information Under 1 CFR Part 51

We reviewed GE SB CF6–80C2 S/B 72–1520, dated September 22, 2015 and GE SB CF6–80E1 S/B 72–0525, dated September 22, 2015. These SBs describe the procedures for removing and replacing the accessory heat shield assembly. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Other Related Service Information

We reviewed GE SB CF6–80E1 S/B 72–0504, dated October 24, 2014. This SB describes procedures for quick-turn workscope procedure to replace CF6–80E1 stage 1 high-pressure turbine blades. We also reviewed GE SB CF6–80C2 S/B 72–1516, Revision 2, dated November 6, 2015. This SB describes procedures for replacement of the CRF assembly, oil manifold, air tubes, and support brackets. We also reviewed GE SB CF6–80C2 S/B 72–1523, dated September 22, 2015. This SB describes procedures for removing and replacing the accessory heat shield assembly.

Costs of Compliance

We estimate that this AD affects 935 engines installed on airplanes of U.S. registry. We also estimate that it will take about 5 hours per engine to comply with this AD. The average labor rate is $85 per hour. Parts cost about $14,207 per engine. Based on these figures, we estimate the total cost of this AD to U.S. operators to be $13,680,920.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a "significant regulatory action" under Executive Order 12866,

(2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2016–08–10 General Electric Company: Amendment 39–18486; Docket No. FAA–2015–4344; Directorate Identifier 2015–NE–32–AD.

(a) Effective Date

This AD is effective June 1, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all General Electric Company (GE) CF6–80C2A1, CF6–80C2A2, CF6–80C2A3, CF6–80C2A5, CF6–80C2A5F, CF6–80C2A8, CF6–80C2B1, CF6–80C2B1F, CF6–80C2B1F1, CF6–80C2B1F2, CF6–80C2B2, CF6–80C2B2F, CF6–80C2B3F, CF6–80C2B4, CF6–80C2B4F, CF6–80C2B5F, CF6–80C2B6, CF6–80C2B6F, CF6–80C2B6FA, CF6–80C2B7F, CF6–80C2B8F, CF6–80C2D1F, CF6–80C2L1F, CF6–80C2K1F turbofan engines. This AD also applies to CF6–80E1A1, CF6–80E1A2, CF6–80E1A3, CF6–80E1A4, and CF6–80E1A4/B turbofan engines.

(d) Unsafe Condition

This AD was prompted by reports of a burn-through of the accessory heat shield during an engine fire, leading to an accessory compartment fire. We are issuing this AD to prevent uncontrolled engine fire, and damage to the airplane.

(e) Compliance

Comply with this AD within the compliance times specified, unless already done.

(1) For CF6–80C2 engines, at the next engine shop visit after the effective date of this AD, remove from service accessory heat shield assembly, part number (P/N) 1643M23G12, and any other accessory heat shield assembly listed by P/N in Table 1 of GE Service Bulletin (SB) CF6–80C2 S/B 72–1520, dated September 22, 2015. Install an accessory heat shield assembly eligible for installation.

(2) For CF6–80E1 engines, at the next engine shop visit after the effective date of this AD, remove from service accessory heat shield assemblies listed by P/N in Table 1 of GE SB CF6–80E1 S/B 72–0525, dated September 22, 2015. Install an accessory heat shield assembly eligible for installation.

(3) Remove any heat shield assembly from service if the accessory heat shield assembly part number marking is illegible and the documentation associated with the part cannot properly identify the part.

(f) Installation Prohibition

After the effective date of this AD, do not install any accessory heat shield assembly, P/N 1643M23G12; or any accessory heat shield assembly listed by P/N in Table 1 of GE SB CF6–80C2 S/B 72–1520, dated September 22, 2015; or in Table 1 of GE SB CF6–80E1 S/B 72–0525, dated September 22, 2015; into any engine.

(g) Definition

For the purpose of this AD, an engine shop visit is defined as the induction of an engine into the shop for maintenance involving the separation of any major mating engine flanges, except that the separation of engine flanges solely for the following purposes is not considered a shop visit:

(1) Transportation without subsequent engine maintenance.

(2) Replacement of the turbine rear frame.

(3) Removal of the top or bottom high-pressure compressor (HPC) case, or both, for HPC airfoil maintenance or replacement of variable stator vane bushing or lever arms.

(4) Quick-turn workscope procedure to replace CF6–80E1 stage 1 high-pressure turbine (HPT) blades per CF6–80E1 SB 72–0504 R00 ENGINE—General (72–00–00)—Quick-Turn Workscope Procedure to Replace CF6–80E1 Stage 1 HPT Blades.

(5) Replacement of compressor rear frame assembly, new oil manifold, air tubes and support brackets per CF6–80C2 SB 72–1516 R02 ENGINE—Compressor Rear Frame Assembly (72–34–00)—New Oil Manifold, Air Tubes and Support Brackets.

(h) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs to this AD. Use the procedures found in 14 CFR 39.19 to make your request. You may email your request to: *ANE-AD-AMOC@faa.gov.*

(i) Related Information

For more information about this AD, contact Herman Mak, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7147; fax: 781–238–7199; email: *herman.mak@faa.gov.*

(j) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) General Electric Company (GE) Service Bulletin (SB) CF6–80C2 S/B 72–1520, dated September 22, 2015.

(ii) GE SB CF6–80E1 S/B 72–0525, dated September 22, 2015.

(3) For GE service information identified in this AD, contact General Electric Company, GE Aviation, Room 285, 1 Neumann Way, Cincinnati, OH 45215; phone: 513–552–3272; email: *aviation.fleetsupport@ge.com.*

(4) You may view this service information at FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

(5) You may view this service information at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Burlington, Massachusetts, on April 7, 2016.

Colleen M. D'Alessandro,

Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2016–09686 Filed 4–26–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9750]

RIN 1545–BN59

Reporting of Original Issue Discount on Tax-Exempt Obligations; Basis and Transfer Reporting by Securities Brokers for Debt Instruments and Options; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations; correction.

SUMMARY: This document contains corrections to final regulations (TD 9750) that published in the **Federal Register** on Thursday, February 18, 2016 (81 FR 8149). The final regulations relates to information reporting by brokers for transactions involving debt instruments and options, including the reporting of original issue discount (OID) on tax-exempt obligations, the treatment of certain holder elections for reporting a taxpayer's adjusted basis in a debt instrument, and transfer reporting for section 1256 options and debt instruments.

DATES: This correction is effective April 27, 2016 and applicable February 18, 2016.

FOR FURTHER INFORMATION CONTACT: Pamela Lew at (202) 317–7053 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulation (TD 9750) that is the subject of this correction is under section 6045 of the Internal Revenue Code.

Need for Correction

As published, the final regulation (TD 9750) contains errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the final regulation (TD 9750), that is the subject of FR Doc. 2016–03429, is corrected as follows:

1. On page 8151, in the preamble, third column, third line from the bottom of the first full paragraph, "OID and acquisition discount on all tax-" is corrected to read "OID and acquisition premium on all tax-".

2. On page 8151, in the preamble, third column, third line from the bottom of the last full paragraph, "discount for a tax-exempt obligation that" is corrected to read "premium for a tax-exempt obligation that".

Martin V. Franks,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 2016–09698 Filed 4–26–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9750]

RIN 1545–BM59

Reporting of Original Issue Discount on Tax-Exempt Obligations; Basis and Transfer Reporting by Securities Brokers for Debt Instruments and Options; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains corrections to final regulations (TD 9750) that were published in the **Federal Register** on Thursday, February 18, 2016 (81 FR 8149). The final regulations relate to information reporting by brokers for transactions involving debt instruments and options, including the reporting of original issue discount (OID) on tax-exempt obligations, the treatment of certain holder elections for reporting a taxpayer's adjusted basis in a debt instrument, and transfer reporting for section 1256 options and debt instruments.

DATES: This correction is effective April 27, 2016 and applicable February 18, 2016.

FOR FURTHER INFORMATION CONTACT: Pamela Lew at (202) 317–7053 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9750) that are the subject of this correction are under section 6045, 6045A, and 6049 of the Internal Revenue Code.

Need for Correction

As published, the final regulations (TD 9750) contain errors that may prove to be misleading and are in need of clarification.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR part 1 is corrected by making the following correcting amendments:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.6045–1 is amended by revising the third sentence of paragraph (n)(4) to read as follows:

§ 1.6045–1 Returns of information of brokers and barter exchanges.

* * * * *

(n) * * *

(4) * * * See paragraph (n)(11) of this section for the treatment of an election described in paragraph (n)(4)(iii) of this section (election to accrue market discount based on a constant yield) and an election described in paragraph (n)(4)(iv) of this section (election to treat all interest as OID).

* * * * *

§ 1.6045A–1 [Corrected]

■ **Par. 3.** Section 1.6045A–1 is amended by removing "and;" at the end of paragraphs (b)(3)(ix) and (b)(4)(iii) and adding "; and" in its place.

§ 1.6049–9 [Corrected]

■ **Par. 4.** Section 1.6049–9(c) is amended by revising the citation "§ 1.6049–10T" to read "§ 1.6049–10" in the last sentence.

Martin V. Franks,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 2016–09697 Filed 4–26–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 42

[Docket No. PTO–P–2015–0053]

RIN 0651–AD01

Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board; Correction

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Final rule; correction.

SUMMARY: The United States Patent and Trademark Office (Office) published a final rule in the **Federal Register** on

April 1, 2016, revising the rules related to trial practice for *inter partes* review, post-grant review, the transitional program for covered business method patents, and derivation proceedings that implemented provisions of the Leahy-Smith America Invents Act ("AIA") providing for trials before the Office. This document corrects an error in that final rule.

DATES: *Effective Date:* This rule is effective May 2, 2016 and applies to all AIA petitions filed on or after the effective date and to any ongoing AIA preliminary proceeding or trial before the Office.

FOR FURTHER INFORMATION CONTACT: Susan L. C. Mitchell, Lead Administrative Patent Judge, by telephone at (571) 272–9797.

SUPPLEMENTARY INFORMATION: The Office published a final rule in the **Federal Register** on April 1, 2016 (81 FR 18750), entitled "Amendments to the Rules of Practice for Trials Before the Patent Trial and Appeal Board." This document corrects an error in § 42.24(a)(1).

The second sentence of § 42.24(a)(1) should state that the word count or page limit does not include a table of contents, a table of authorities, mandatory notices under § 42.8, a certificate of service or word count, or appendix of exhibits or claim listing. The reference to "grounds for standing under § 42.104, § 42.204, or § 42.304" was inadvertently included as administrative items, such as mandatory notices, and in the related discussion in the preamble on pages 18762 and 18763 of the final rule published on April 1, 2016 (81 FR 18750). This correction removes that reference from § 42.24(a)(1).

In rule FR Doc. 2016–07381, published on April 1, 2016 (81 FR 18750), make the following correction:

§ 42.24 [Correction]

1. On page 18765, in the second column, in paragraph (a)(1) of § 42.24, correct the second sentence by removing "grounds for standing under § 42.104, § 42.204, or § 42.304,".

Dated: April 21, 2016.

Michelle K. Lee,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2016–09814 Filed 4–26–16; 8:45 am]

BILLING CODE 3510–16–P

FEDERAL MARITIME COMMISSION

46 CFR Part 535

[Docket No. 16–09]

RIN 3072–AC65

Optional Method of Filing Ocean Common Carrier and Marine Terminal Operator Agreements Subject to the Shipping Act of 1984

AGENCY: Federal Maritime Commission.

ACTION: Direct final rule; and request for comments.

SUMMARY: The Federal Maritime Commission (FMC or Commission) amends its regulations relating to the method of filing Ocean Common Carrier and Marine Terminal Operator Agreements to provide for optional filing of these agreements through a new electronic filing system. This optional filing system is intended to facilitate more efficient filing, review, and publication of these agreements.

DATES: This rule is effective without further action on June 13, 2016, unless significant adverse comment is received by May 27, 2016. If significant adverse comment is received, the Federal Maritime Commission will publish a timely withdrawal of the rule in the **Federal Register**.

ADDRESSES: You may submit comments by the following methods:

- *Email: secretary@fmc.gov.* Include in the subject line: "Docket No. 16–09, Commentor/Company name." Comments should be attached to the email as a Microsoft Word or text-searchable PDF document. Only non-confidential and public versions of confidential comments should be submitted by email.
- *Mail:* Karen V. Gregory, Secretary, Federal Maritime Commission, 800 North Capitol Street NW., Washington, DC 20573–0001. *Phone:* (202) 523–5725. *Email: secretary@fmc.gov.*

Docket: For access to the docket to read background documents or comments received, go to the Commission's Electronic Reading Room at: *http://www.fmc.gov/16-09.*

Confidential Information: The Commission will provide confidential treatment for identified confidential information to the extent allowed by law. If your comments contain confidential information, you must submit the following:

- A transmittal letter requesting confidential treatment that identifies the specific information in the comments for which protection is sought and demonstrates that the information is a trade secret or other confidential research, development, or commercial information.
- A confidential copy of your comments, consisting of the complete filing with a cover page marked "Confidential-Restricted," and the confidential material clearly marked on each page. You should submit the confidential copy to the Commission by mail.
- A public version of your comments with the confidential information excluded. The public version must state "Public Version—confidential materials excluded" on the cover page and on each affected page, and must clearly indicate any information withheld. You may submit the public version to the Commission by email or mail.

FOR FURTHER INFORMATION CONTACT: For questions regarding submitting comments or the treatment of confidential information, contact Karen V. Gregory, Secretary, *Phone:* (202) 523–5725. *Email: secretary@fmc.gov.* For technical questions, contact Florence A. Carr, Director, Bureau of Trade Analysis. *Phone:* (202) 523–5796. *Email: tradeanalysis@fmc.gov.* For legal questions, contact Tyler J. Wood, General Counsel. *Phone:* (202) 523–5740. *Email: generalcounsel@fmc.gov.*

SUPPLEMENTARY INFORMATION: On January 18, 2011, President Obama issued Executive Order 13563 (E.O. 13563) to emphasize the importance of public participation in adopting regulations, integration and innovation in regulatory actions, flexible approaches in achieving regulatory objectives, and ensuring the objectivity of any scientific and technological information and process in regulatory actions. E.O. 13563 requires executive agencies to develop a plan to periodically review their existing significant regulations to determine whether any such regulations should be modified, streamlined, expanded, or repealed so as to make such agencies' regulatory programs more effective and less burdensome in achieving the regulatory objectives. On July 11, 2011, Executive Order 13579 was issued to encourage independent regulatory agencies to also pursue the goals stated in E.O. 13563.

On November 4, 2011, the Commission issued its *Plan for Retrospective Review of Existing Rules* (Plan) and invited public comment on how it might improve the current regulations.[1] The Plan included a review schedule for the Commission's existing regulations, which was updated on February 13, 2013. Among the comments received in response to the Plan were the *Comments of Ocean Common Carriers* on May 18, 2012.[2]

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[1] A copy of the Plan and comments filed in response to the Plan that are within the scope of this rulemaking have been placed in the docket.

The carriers' comments included a request for the Commission to "adopt rules and procedures pursuant to which carrier and marine terminal operator agreements can be filed electronically." The carriers pointed out that "virtually all filings made with the Commission, other than agreement filings, are made electronically (*e.g.*, agreement minutes, monitoring reports and guidelines, OTI license applications)" and noted that "[i]ronically, the Commission maintains an electronic library of agreements on its Web site, so these agreements are retained electronically in any event." While the carriers conclude that the electronic filing of agreements "would reduce the burden and expense of filing for the industry," the Commission notes that doing so would also streamline its internal business processes, thereby resulting in a more efficient regulatory process and expediting public access to agreement filings through the Commission's Web site. These benefits are consistent with Executive Order 13579.

Under the Commission's existing rules at 46 CFR 535.401, "a true copy and seven additional copies of the executed agreement" must be submitted in paper format to the Commission's Secretary during the regular business hours of 8:30 a.m. to 5:00 p.m., Monday through Friday. The agreement's filing must be accompanied by a letter of transmittal, and, where required, an original and five copies of the completed Information Form, also in paper format. To respond to the industry's request to reduce the regulatory burden associated with the filing of multiple copies of agreements and supporting documents in paper format, the Commission determined that automating the agreement filing process should be given priority.

The FMC's Office of Information Technology (OIT), in conjunction with the Bureau of Trade Analysis (BTA), commenced efforts in October 2015 to automate the process of filing agreements with the Commission. BTA met with various agreement filers during development to ensure that the new system would not only provide a user-oriented electronic filing environment but also deliver more robust public search capabilities for the online agreement library based on a variety of filters. Further enhancement of the online agreement library's search capabilities is planned in the future.

Initial software development and associated testing to support the electronic agreement filing system has been completed. The Commission now plans to make this technology available as an optional method to file agreements and supporting documents. Use of the automated system will not be required, however, as parties may continue to submit agreements in paper format. Paper filings will be received and processed in the same manner as before.

Under the new electronic agreement filing system, supporting documentation previously submitted in paper form may also be appended electronically as part of the filing process. Validity checks incorporated into the automated filing process will allow the filer to verify Commission information regarding agreement parties, thereby ensuring a more accurate public online agreement library, as well as facilitating review and oversight of agreements by the Commission. The system may be accessed through the Commission's Web site at *http://www.fmc.gov* under Public FMC Databases/Agreement Notices and Library. Prospective filers may register for the electronic agreement filing system and obtain a login and password by following the instructions on the system's Web page. As with current practice, the public will have the ability to view all agreements in the online agreement library; however, the public will not be able to view the filer's letter of transmittal and Information Form, if any. In addition, the filing system is password-protected to ensure the security of information being collected, primarily in supporting documents, and to appropriately restrict external filing permission to the agreement filer and its authorized filing agents.

The Commission's rules presently require that each agreement and modification filed must be signed by an official or authorized representative of each of the parties and that the original signature page(s) accompany the agreement's filing. The rules allow some measure of flexibility to filers by permitting faxed or photocopied signatures to accompany the agreement's filing if the copies are replaced with original signatures prior to the agreement's effective date. § 535.403(d). Many times, the individuals who sign an agreement are located overseas or are traveling and may be required to transmit a signature page electronically to filing counsel in order to expedite an agreement's filing, and consequently, its effectiveness. In such cases, agreement counsel submits a photocopy of the parties' signature pages with the agreement's filing, and must follow up by sending the original signatures by mail or courier to the Commission prior to the effective date.

While the Commission's rules presently require that the original signatures of the parties executing an agreement must be filed with the Commission, the Shipping Act of 1984 (the Act) 46 U.S.C. 40101 *et seq.*, provides only that "a true copy of every agreement . . . shall be filed with the Federal Maritime Commission" and permits the Commission to prescribe the form and manner in which agreements are filed. 46 U.S.C. 40302(a), (c). As the Act does not require the filing of the original agreement with the Commission, removing the parties' requirement to provide original signatures with an agreement's filing would eliminate an unnecessary regulatory burden. The Commission is, therefore, removing this requirement and will begin accepting photocopies and scanned electronic copies of the agreement parties' original signatures. The Commission is similarly removing the requirement that transmittal letters accompanying agreement filings include an original signature.

Congressional Review Act

The rule is not a "major rule" as defined by the Congressional Review Act, codified at 5 U.S.C. 801 *et seq.* The rule will not result in: (1) An annual effect on the economy of $100,000,000 or more; (2) a major increase in costs or prices; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based companies to compete with foreign-based companies. 5 U.S.C. 804(2).

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, the Chairman of the Federal Maritime Commission certifies that this direct final rule will not have a significant economic impact on a substantial number of small entities. The rule applies to the filing requirements for agreements by or among vessel-operating common carriers (VOCCs) and/or marine terminal operators (MTOs). The Commission has previously determined that VOCCs and MTOs do not qualify as small entities because the number of employees and/or gross receipts of these regulated businesses typically exceed the thresholds set under the guidelines of the Small Business Administration.[3] This rule implements an alternative electronic method for filing agreements with the Commission that is optional for the industry. The current regulations require that agreements be filed with the Commission in paper form. The new electronic system should significantly reduce the burden and expense of filing on the industry. Further, in comments to the Commission's *Plan for the Retrospective Review of Existing Rules,* a majority of VOCCs specifically requested that the Commission implement an electronic system for filing agreements.

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[2] The commenting carriers consisted of a total of thirty ocean carriers participating in the following agreements active at that time: The fourteen members of the Transpacific Stabilization Agreement (TSA); ten members of the Westbound Transpacific Stabilization Agreement (WTSA); six members of the Central America Discussion Agreement (CADA); eleven members of the West Coast South America Discussion Agreement (WCSADA); five members of the Venezuela Discussion Agreement (VDA); three members of the ABC Discussion Agreement (ABCDA); six members of the United States Australasia Discussion Agreement (USADA); and, the three members of the Australia New Zealand United States Discussion Agreement (ANZUSDA). The carriers' recommendations with respect to agreements, with one exception, are being considered by the Commission under FMC Docket No. 16–04. See Advance Notice of Proposed Rulemaking, *Ocean Common Carrier and Marine Terminal Operator Agreements Subject to the Shipping Act of 1984*, 81 FR 10188 (Feb. 29, 2016). The exception referenced is the subject of this rulemaking.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) requires an agency to seek and receive approval from the Office of Management and Budget (OMB) before collecting information from the public and before making substantive or material modifications to a previously approved information collection. 44 U.S.C. 3507; 5 CFR 1320.5(a), (g). The information-collection contained in Part 535, including the agreement-filing requirements, have been approved by OMB and assigned OMB Control Number 3072–0046. The Commission is modifying this information collection by allowing electronic filing of agreements and expects that this change will reduce the paperwork burdens on regulated entities. The Commission will, however, continue to allow paper filing of agreements. Accordingly, this modification is neither substantive nor material. The expiration date for the Part 535 information collection is November 30, 2016, and the Commission will note the modification and any resulting changes to the burden hour estimate when it seeks an extension of the information collection later this year.

Direct Final Rule Justification

The Commission expects the amendments to be noncontroversial. Under the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), a final rule may be issued without notice and comment when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest. This rule provides an optional electronic method of filing agreements and supporting documents as a more flexible and less burdensome alternative for the regulated parties to those agreements, and maintains the present paper format filing procedures for filers that wish to continue utilizing the current method. The electronic agreement filing system was developed at the behest, in 2012, of thirty global ocean common carriers participating in the major rate discussion agreements filed with the Commission to relieve the regulatory burden of paper filings. Further, the requirement to include original signatures to agreements and transmittal letters, rather than photo- or electronic copies, burdens filers and appears to provide limited, if any, public benefit. Thus, the Commission has determined that providing an opportunity for comment is unnecessary.

Therefore, pursuant to 5 U.S.C. 553, notice and comment are not required and this rule may become effective after publication in the **Federal Register**, unless the Commission receives significant adverse comments within the specified period. The Commission recognizes that parties may have information that could impact the Commission's views and intentions with respect to the revised regulations, and the Commission intends to consider any comments filed. The Commission will withdraw the rule if it receives significant adverse comments. Filed comments that are not adverse may be considered for modifications to Part 535 at a future date.

If no significant adverse comment is received, the rule will become effective 15 days after the close of the comment period without additional action. The Administrative Procedure Act generally requires a minimum of 30 days before a final rule can go into effect, but excepts from this requirement rules that relieve a restriction. 5 U.S.C. 553(d)(1). Because this final rule provides for an additional, optional method of filing agreements and removes the requirement that agreement filings and accompanying transmittal letters include original signatures, the rule falls within this exception.

List of Subjects in 46 CFR Part 535

Freight, Maritime carriers, Reporting and recordkeeping requirements.

Regulatory Text

For the foregoing reasons, the Commission amends 46 CFR part 535 as follows:

PART 535—OCEAN COMMON CARRIER AND MARINE TERMINAL OPERATOR AGREEMENTS SUBJECT TO THE SHIPPING ACT OF 1984

■ 1. The authority citation for part 535 continues to read as follows:

Authority: 5 U.S.C. 553; 46 U.S.C. 305, 40101–40104, 40301–40307, 40501–40503, 40901–40904, 41101–41109, 41301–41302, and 41305–41307.

■ 2. Amend § 535.401 by revising paragraphs (a) and (b)(4) to read as follows:

§ 535.401 General requirements.

(a) All agreements (including oral agreements reduced to writing in accordance with the Act) subject to this part and filed with the Commission for review and disposition pursuant to section 6 of the Act (46 U.S.C. 40304, 40306, 41307(b)–(d)), must be submitted to the Commission either in paper during regular business hours to the Secretary, Federal Maritime Commission, Washington, DC 20573, or electronically using the automated agreement filing system.

(1) *Paper filings.* Paper filings must include:

(i) A true copy and seven additional copies of the executed agreement;

(ii) Where required by this part, an original and five copies of the completed Information Form referenced at subpart E of this part; and

(iii) A letter of transmittal as described in paragraph (b) of this section.

(2) *Electronic filings.* (i) Electronic filings using the automated agreement filing system must be made in accordance with the instructions found on the Commission's home page, *http://www.fmc.gov.*

(ii) Electronic filings must include searchable Portable Document Format (PDF) copies of the following:

(A) A true copy of the executed agreement;

(B) Where required by this part, a completed Information Form referenced at subpart E of this part; and

(C) A letter of transmittal as described in paragraph (b) of this section.

(b) * * *

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[3] See *FMC Policy and Procedures Regarding Proper Considerations of Small Entities in Rulemakings,* page 4 (February 7, 2003), from the Web site of the FMC at *http://www.fmc.gov/assets/1/Page/SBREFA_Guidelines_2003.pdf.*

(4) Be signed by the filing party or on the filing party's behalf by an authorized employee or agent of the filing party. A faxed, photocopied, or scanned signature will be accepted.

* * * * *

■ 3. Amend § 535.403 by revising paragraph (d) to read as follows:

§ 535.403 Form of agreements.

* * * * *

(d) Each agreement and/or modification filed must be signed by an official or authorized representative of each of the parties and must indicate the typewritten full name of the signing party and his or her position, including organizational affiliation. Faxed, photocopied, or scanned signatures will be accepted.

* * * * *

■ 4. Amend § 535.501 by revising the last sentence of paragraph (b) to read as follows:

§ 535.501 General requirements.

* * * * *

(b) * * * In lieu of submitting paper copies, parties may complete and submit their Information Form in the Commission's prescribed electronic format, either on diskette or CD–ROM, or submit the Information Form using the automated agreement filing system in accordance with the instructions found on the Commission's home page, *http://www.fmc.gov.*

* * * * *

By the Commission.

Karen V. Gregory,

Secretary.

[FR Doc. 2016–09760 Filed 4–26–16; 8:45 am]

BILLING CODE 6731–AA–P

DEPARTMENT OF STATE

48 CFR Parts 601, 606, 608, 615, 616, 623, 627, 633, 651, and 652

[Public Notice: 9482]

RIN 1400–AD92

Department of State Acquisition Regulation; Technical Amendments

AGENCY: Department of State.

ACTION: Final rule; technical amendments.

SUMMARY: The Department of State is amending the Department of State Acquisition Regulation (DOSAR) to make non-substantive corrections and editorial changes.

DATES: This rule is effective April 27, 2016.

ADDRESSES: You may submit comments using the following method:

- *Email: KosarCM@state.gov.* You must include the RIN in the subject line of your message.

FOR FURTHER INFORMATION CONTACT: Ms. Colleen Kosar, Policy Division, Office of the Procurement Executive, A/OPE, 2201 C Street NW., Suite 1060, State Annex Number 15, Washington, DC 20520. Telephone: 703–516–1685. Email: *KosarCM@state.gov.*

SUPPLEMENTARY INFORMATION: This document updates Parts 601, 606, 608, 615, 616, 623, 627, 633, 651 and 652 to correct formatting, grammatical, numbering and wording errors/oversights as follows—

1. Corrects a cross reference in DOSAR 601.602–1(b);
2. Corrects a grammatical error in DOSAR 606.304(a)(2);
3. Corrects the title of DOSAR 606.5;
4. Corrects terminology in DOSAR 606.501(b) to align with a recent FAR change;
5. Adds a delegation of authority in DOSAR 608.405–3(a)(3)(ii);
6. Removes "DOSAR" from DOSAR 615.205–70 to comply with the referencing convention cited at DOSAR 601.303(c);
7. Corrects the title of DOSAR 616.103;
8. Adds a delegation of authority in DOSAR 616.504(c)(1)(ii)(D)*(1)*
9. Adds a paragraph identifier to the text of DOSAR 623.506;
10. Adds a clarification to DOSAR 627.304–1;
11. Adds a missing section heading for DOSAR 633.214;
12. Retitles DOSAR 633. 214–70;
13. Redesignates 651.701 as 651.7001;
14. Corrects the capitalization of "subpart" in DOSAR 652.100–70(a) and (b) to comply with the referencing convention cited at DOSAR 601.303(c);
15. Corrects the title of DOSAR subpart 652.2; and
16. Corrects a reference in the introductory text of DOSAR 652.232–72.

Regulatory Findings

Administrative Procedure Act

The Department is publishing this rule as a direct final rule, as an interpretative rule, general statement of policy, or rule of agency organization, procedure, or practice, in accordance with 5 U.S.C. 553(b). The effective date of this rulemaking is the date of publication, in accordance with 5 U.S.C. 553(d). The Department finds good cause for this rule to be effective immediately. Since the amendments in this rule are merely technical in nature or address the internal operating procedures of the agency, public comment is unnecessary.

Regulatory Flexibility, Unfunded Mandates, SBREFA

The Department of State, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and, by approving it, certifies that this rule will not have a significant economic impact on a substantial number of small entities. This determination was based on the fact that the amendments in this rule will not have any cost or administrative impact on offerors or contractors. Thus, it was concluded that the rule will not have a significant economic impact on a substantial number of small entities. This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Act of 1995. Finally, this rule is not a major rule as defined by the Small Business Regulatory Enforcement Act of 1996 (5 U.S.C. 801 *et seq.*).

Executive Orders 12866 and 13563

The Department of State does not consider this rule to be an "economically significant" regulatory action under E. O. 12866. The Department has reviewed the regulation to ensure its consistency with the regulatory philosophy and principles set forth in Executive Orders 12866 and 13563 and finds that the benefits of updating this rule outweigh any costs, which the Department assesses to be minimal.

Executive Order 13132 and 13175

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. The Department has determined that this rulemaking will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not pre-empt tribal law.

Paperwork Reduction Act

The rule imposes no new or revised information collections under the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35).

List of Subjects in 48 CFR Parts 601, 606, 608, 615, 616, 623, 627, 633, 651 and 652

Administrative practice and procedure, Government procurement.

For the reasons stated in the preamble, the Department of State amends 48 CFR chapter 6 as follows:

■ 1. The authority citation for 48 CFR parts 601, 606, 608, 615, 616, 623, 627, 633, 651 and 652 continues to read as follows:

Authority: 22 U.S.C. 2651a, 40 U.S.C. 121(c) and 48 CFR chapter 1.

PART 601—DEPARTMENT OF STATE ACQUISITION REGULATION SYSTEM

601.602–1 [Amended]

■ 2. In section 601.602–1, paragraph (b), remove "601.603–70" and add in its place "601.601–70".

PART 606—COMPETITION REQUIREMENTS

606.304 [Amended]

■ 3. In section 606.304, in paragraph (a)(2), remove "a advocate for competition" and add in its place "an advocate for competition".

Subpart 606.5—Advocates for Competition

■ 4. Revise the heading for subpart 606.5 to read as set forth above.

■ 5. In section 606.501, in the second sentence of paragraph (b), remove "competition advocate" and add in its place "advocate for competition".

PART 608—REQUIRED SOURCES OF SUPPLIES AND SERVICES

■ 6. Add subpart 608.4 to read as follows:

Subpart 608.4—Federal Supply Schedules

608.405 Ordering procedures for Federal Supply Schedules.
608.405–3 Blanket Purchase Agreements.

Subpart 608.4—Federal Supply Schedules

608.405 Ordering procedures for Federal Supply Schedules.

608.405–3 Blanket Purchase Agreements.

(a) *Establishment.*

(3)(ii) The Procurement Executive is the head of the agency for the purposes of FAR 8.405–3(a)(3)(ii).

PART 615—CONTRACTING BY NEGOTIATION

615.205–70 [Amended]

■ 7. In section 615.205–70, remove "DOSAR".

PART 616—TYPES OF CONTRACTS

■ 8. Revise the heading for section 616.103 to read as follows:

616.103 Negotiating contract type.

* * * * *

■ 9. Add section 616.504 to read as follows:

616.504 Indefinite-quantity contracts.

(c) *Multiple award preference*—(1) *Planning the acquisition.*

(ii)(D)*(1)* The Procurement Executive is the head of the agency for the purposes of FAR 16.504(c)(1)(ii)(D)*(1)*.

PART 623—ENVIRONMENT, ENERGY AND WATER EFFICIENCY, RENEWABLE ENERGY TECHNOLOGIES, OCCUPATIONAL SAFETY, AND DRUG-FREE WORKPLACE TYPES OF CONTRACTS

623.506 [Amended]

■ 10. The text of section 623.506 is designated as paragraph (e).

PART 627—PATENTS, DATA, AND COPYRIGHTS

627.304–1 [Amended]

■ 11. In the third sentence of section 627.304–1, add "proposed to be" between "Determinations" and "issued".

PART 633—PROTESTS, DISPUTES, AND APPEALS

Subpart 633.214—Alternative dispute resolution (ADR)

■ 12. Add a subpaart 633.214 heading to read as set forth above.

■ 13. Revise the heading for section 633.214–70 to read as follows:

633.214–70 DOS ADR program.

* * * * *

PART 651—USE OF GOVERNMENT SOURCES BY CONTRACTORS

651.701 [Redesignated as 651.7001]

■ 14. Section 651.701 is redesignated as section 651.7001.

PART 652—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

652.100–70 [Amended]

■ 15. In section 652.100–70, revise "Subpart" to read "subpart" in paragraphs (a) and (b).

Subpart 652.2—Text of Provisions and Clauses

■ 16. Revise the subpart 652.2 heading to read as set forth above.

652.232–72 [Amended]

■ 17. In the introductory text of section 652.232–72, remove "632.705–70" and add in its place "632.706–70".

Corey M. Rindner,
Procurement Executive, Department of State.

[FR Doc. 2016–09570 Filed 4–26–16; 8:45 am]

BILLING CODE 4710–24–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R3–ES–2016–0052; 4500030113]

RIN 1018–AZ62

Endangered and Threatened Wildlife and Plants; Determination That Designation of Critical Habitat Is Not Prudent for the Northern Long-Eared Bat

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Critical habitat determination.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), have reconsidered whether designating critical habitat for the northern long-eared bat (*Myotis septentrionalis*) is prudent. We have determined that such a designation is not prudent. We listed the northern long-eared bat as a threatened species under the Endangered Species Act of 1973, as amended (Act), on April 2, 2015. At the time the species was listed, we determined that designation of critical habitat was prudent, but not determinable. Since that time, information has come available that demonstrates that designating the wintering habitat as critical habitat for the bat would likely increase the threat from vandalism and disturbance, and could, potentially, increase the spread of white-nose syndrome. In addition, designating the summer habitat as critical habitat would not be beneficial to the species, because there are no areas within the summer habitat that meet the definition of critical habitat. Thus, we have determined that the designation of critical habitat is not prudent for the northern long-eared bat.

DATES: The determination announced in this document was made on April 27, 2016.

ADDRESSES: This document is available on the Internet at *http://www.regulations.gov* at Docket No. FWS–R3–ES–2016–0052. Supporting documentation we used in preparing this document will be available for public inspection, by appointment, during normal business hours at the Twin Cities Ecological Services Office, U.S. Fish and Wildlife Service, 4101 American Blvd. E., Bloomington, MN 55425.

FOR FURTHER INFORMATION CONTACT: Peter Fasbender, Field Supervisor, 952–252–0092, extension 210. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Background

The northern long-eared bat (*Myotis septentrionalis*) is a wide-ranging species that is found in a variety of forested habitats in summer and hibernates in caves and mines (or habitat with similar conditions to suitable caves or mines) in winter. The fungal disease, white-nose syndrome (WNS), is the main threat to this species and has caused a precipitous decline in bat numbers (in many cases, 90–100 percent) where the disease has occurred. Declines in the numbers of northern long-eared bats are expected to continue as WNS extends across the species' range, provided no cure to the disease is found. For more information on the northern long-eared bat, its habitat, and WNS, please refer to the October 2, 2013, proposed listing (78 FR 61046) and the April 2, 2015, final listing (80 FR 17974) rules.

Summer Habitat

Suitable summer habitat for the northern long-eared bat consists of a wide variety of forested and wooded habitats where they roost, forage, and travel (Foster and Kurta 1999, p. 668), and may also include some adjacent and interspersed non-forested habitats (Yates and Muzika 2006, p. 1,245). This includes forests and woodlots containing potential roosts, as well as linear features such as fence rows, riparian forests, and other wooded corridors. These wooded areas may be dense or loose aggregates of trees with variable amounts of canopy closure (Lacki and Schwierjohann 2001, p. 487; Perry and Thill 2007, p. 223; Sasse and Pekins 1996, p. 95; Timpone *et al.* 2010, p. 118).

After hibernation ends in late March or early April (as late as May in some northern areas), most northern long-eared bats migrate to summer roosts. The spring migration period typically runs from mid-March to mid-May (Caire *et al.* 1979, p. 405; Easterla 1968, p. 770; Whitaker and Mumford 2009, p. 207). The northern long-eared bat is not considered to be a long-distance migrant (typically 40–50 miles (64–80 kilometers)). Males and non-reproductive females may summer near or in their winter habitat (hibernacula), or migrate to summer habitat some distance from their hibernaculum.

After emerging from hibernacula in the spring, female northern long-eared bats actively form colonies in the summer (Foster and Kurta 1999) and exhibit fission-fusion behavior (Garroway and Broders 2007), where members frequently coalesce to form a group, but composition of the group is in flux (Barclay and Kurta 2007, p. 44). As part of this behavior, northern long-eared bats switch tree roosts often (Sasse and Pekins 1996, p. 95), typically every 2 to 3 days (Foster and Kurta 1999, p. 665; Owen *et al.* 2002, p. 2; Carter and Feldhamer 2005, p. 261; Timpone *et al.* 2010, p. 119). Northern long-eared bat maternity colonies range widely in size (reported range of 7 to 100; Owen *et al.* 2002, p. 2; Whitaker and Mumford 2009, p. 212), although colonies of 30–60 individuals may be most common, at least prior to the onset of WNS (Whitaker and Mumford 2009, p. 212; Caceres and Barclay 2000, p. 3; Service 2014, p. A16).

Northern long-eared bats show interannual fidelity to roost trees and maternity areas. They use networks of roost trees often centered around one or more central-node roost trees (Johnson *et al.* 2011, p. 228) with multiple alternate roost trees. Northern long-eared bats roost in cavities, crevices, hollows, or underneath bark of both live and dead trees and snags (typically ≥3 inches (in) (8 centimeters (cm)) in diameter at breast height (dbh)). Northern long-eared bats are known to use a wide variety of roost types, using tree species based on presence of cavities or crevices or presence of peeling bark. Northern long-eared bats have also been found roosting in structures such as buildings, barns, sheds, houses, and bridges (Benedict and Howell 2008, p. 5; Krochmal and Sparks 2007, p. 650; Timpone *et al.* 2010, p. 119; Service 2014, p. 2).

The best available information indicates that northern long-eared bats seem to be flexible in roost selection, using varying roost tree species and types of roosts throughout their range. They do not depend on certain species of trees for roosts; rather, they opportunistically use many tree species that form suitable cavities or retain bark (Foster and Kurta 1999, p. 668). Additionally, the bats may use either live trees or snags; the use of live trees versus snags may reflect the availability of such structures (Perry and Thill 2007, p. 224) and the presence of sympatric bat species (*e.g.*, Indiana bat (*Myotis sodalis*)) (Timpone *et al.* 2010, p. 120), as opposed to a specific preference of tree or other habitat characteristics. Results from studies have also found that the diameters of roost trees selected by northern long-eared bats vary greatly (Sasse and Pekins 1996, pp. 95–96; Schultes 2002, pp. 49, 51; Perry 2014, pers. comm.; Lereculeur 2013, pp. 52–54; Carter and Feldhamer 2005, p. 263; Foster and Kurta 1999, p. 663; Lacki and Schwierjohann 2001, pp. 484–485; Owens *et al.* 2002, p. 3; Timpone *et al.* 2010, p. 118; Lowe 2012, p. 61; Perry and Thill 2007, p. 223; Lacki *et al.* 2009, p. 1,171) and that northern long-eared bats can forage in a variety of forest types (Brack and Whitaker 2001, p. 207; LaVal *et al.* 1977, p. 594; van Zyll de Jong 1985, p. 94). Northern long-eared bats change roost trees frequently (*e.g.*, Cryan *et al.* 2001, p. 50; Foster and Kurta 1999, p. 665) within their summer home range; this behavior suggests they are adapted to responding quickly to changes in roost availability and ephemeral roosts. For a more detailed discussion on summer habitat, refer to the April 2, 2015, final listing rule (80 FR 17974).

Winter Habitat (Hibernacula)

Northern long-eared bats hibernate during the winter months to conserve energy from increased thermoregulatory demands and reduced food resources (Thomas *et al.* 1990, p. 475; Thomas and Geiser 1997, p. 585; Bouma *et al.* 2010, p. 623). Suitable winter habitat includes caves and cave-like structures (*e.g.*, abandoned or active mines, railroad tunnels) (Service 2015, unpublished data; Goehring 1954, p. 435; Kurta *et al.* 1997, p. 478). Other landscape features may be used by northern long-eared bats during the winter, but they have yet to be documented. Generally, northern long-eared bats hibernate from October to April, depending on the local climate (November/December through March in southern areas, with emergence as late as mid-May in some northern areas) (Caire *et al.* 1979, p. 405; Whitaker and Hamilton 1998, p. 100; Amelon and Burhans 2006, p. 72).

Hibernacula used by northern long-eared bats vary in size (Raesly and Gates 1987, p. 20; Kurta 2013, in litt.), and these hibernacula have relatively constant, cooler temperatures (0 to 9 degrees Celsius (°C) (32 to 48 degrees

Fahrenheit (°F)) (Raesly and Gates 1987, p. 18; Caceres and Pybus 1997, p. 2; Brack 2007, p. 744), with high humidity and minimal air currents (Fitch and Shump 1979, p. 2; van Zyll de Jong 1985, p. 94; Raesly and Gates 1987, p. 118; Caceres and Pybus 1997, p. 2). The sites favored by northern long-eared bats are often in very high humidity areas, to such a large degree that droplets of water are often observed on their fur (Hitchcock 1949, p. 52; Barbour and Davis 1969, p. 77). Within hibernacula, northern long-eared bats are typically found roosting in small crevices or cracks in cave or mine walls or ceilings, sometimes with only the nose and ears visible (Griffin 1940, pp. 181–182; Barbour and Davis 1969, p. 77; Caire *et al.* 1979, p. 405; van Zyll de Jong 1985, p. 9; Caceres and Pybus 1997, p. 2; Whitaker and Mumford 2009, pp. 209–210).

To a lesser extent, northern long-eared bats have also been observed overwintering in other types of habitat that resemble cave or mine hibernacula, including abandoned railroad tunnels (Service 2015, unpublished data). Although similar bat species (*e.g.*, big brown bats (*Eptesicus fuscus*)) have been found using non-cave or non-mine hibernacula, including attics and hollow trees (Neubaum *et al.* 2006, p. 473; Whitaker and Gummer 1992, pp. 313–316), northern long-eared bats have only been observed overwintering in suitable caves, mines, or habitat with the same types of conditions found in suitable caves or mines.

Northern long-eared bats tend to roost singly or in small groups (Service 2013, unpublished data), with hibernating population sizes rarely recorded in concentrations of more than 100 bats in a single hibernaculum (Barbour and Davis 1969, p. 77). Northern long-eared bats display more winter activity than other cave species, with individuals occasionally moving between hibernacula throughout the winter (Griffin 1940, p. 185; Whitaker and Rissler 1992, p. 131; Caceres and Barclay 2000, pp. 2–3). Northern long-eared bats have shown a high degree of philopatry (*i.e.*, using the same site multiple years) to the hibernacula used (Pearson 1962, p. 30).

Northern long-eared bat hibernacula have fairly specific physical and biological requirements that make them suitable for northern long-eared bats. In general, bats select hibernacula because they have characteristics that allow the bats to meet specific life-cycle requirements. Factors influencing a hibernaculum's suitability include its physical structure (*e.g.*, openings, interior space, depth), air circulation, temperature profile, and location relative to foraging sites (Tuttle and Stevenson 1978, pp. 108–121). For a more detailed discussion on winter habitat, refer to the April 2, 2015, final listing rule (80 FR 17974).

Previous Federal Actions

Refer to the proposed (78 FR 61046; October 2, 2013) and final (80 FR 17974; April 2, 2015) listing rules for the northern long-eared bat for a detailed description of previous Federal actions concerning this species. On April 2, 2015, we published in the **Federal Register** (80 FR 17974) a final rule listing the northern long-eared bat as a threatened species. In the April 2, 2015, rule, we also established an interim rule under section 4(d) of the Act (16 U.S.C. 1531 *et seq.*). The final listing rule and the interim 4(d) rule both became effective on May 4, 2015. On January 14, 2016 (81 FR 1900), we published a final 4(d) rule, which became effective on February 16, 2016.

Critical Habitat

Background

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12), require that, to the maximum extent prudent and determinable, we designate critical habitat at the time the species is determined to be an endangered or threatened species. Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features

(a) Essential to the conservation of the species, and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Our regulations at 50 CFR 424.02 defines the geographical area occupied by the species as: An area that may generally be delineated around species' occurrences, as determined by the Secretary (*i.e.*, range). Such areas may include those areas used throughout all or part of the species' life cycle, even if not used on a regular basis (*e.g.*, migratory corridors, seasonal habitats, and habitats used periodically, but not solely by vagrant individuals).

Conservation, as defined under section 3 of the Act, means to use, and the use of, all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the requirement that Federal agencies ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Critical habitat designation does not allow the government or public to access private lands, nor does it require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Where a landowner requests Federal agency funding or authorization for an action that may affect a listed species or critical habitat, the Federal agency would be required to consult under section 7(a)(2) of the Act, but even if consultation leads to a finding that the action would likely cause destruction or adverse modification of critical habitat, the resulting obligation of the Federal action agency and the landowner is not to restore or recover the species, but rather to implement reasonable and prudent alternatives to avoid destruction or adverse modification of critical habitat.

Under the first prong of the Act's definition of critical habitat, areas within the geographical area occupied by the species at the time it was listed are included in a critical habitat designation if they contain physical or biological features (1) which are essential to the conservation of the species and (2) which may require special management considerations or protection. For these areas, critical habitat designations identify, to the extent known using the best scientific and commercial data available, those physical or biological features that are essential to the conservation of the species (such as space, food, cover, and protected habitat). In identifying those physical or biological features, we focus on the specific features that support the life-history needs of the species, including but not limited to, water characteristics, soil type, geological features, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic, or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity.

Under the second prong of the Act's definition of critical habitat, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed if we determine that such areas are essential for the conservation of the species. For example, an area that is currently occupied by the species, but was not occupied at the time of listing, may be essential to the conservation of the species and may be included in the critical habitat designation.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines, provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. For example, they require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

Critical Habitat Prudency Determination

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12), require that, to the maximum extent prudent and determinable, we designate critical habitat at the time the species is determined to be an endangered or threatened species. Our regulations (50 CFR 424.12(a)(1)) state that the designation of critical habitat is not prudent when any of the following situations exist: (i) The species is threatened by taking or other human activity, and identification of critical habitat can be expected to increase the degree of threat to the species, or (ii) such designation of critical habitat would not be beneficial to the species. The regulations also provide that, in determining whether a designation of critical habitat would not be beneficial to the species, the factors the Services may consider include but are not limited to: Whether the present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species, or whether any areas meet the definition of "critical habitat" (50 CFR 424.12(a)(1)(ii)).

We have determined that both situations when a critical habitat designation would not be prudent apply to the northern long-eared bat. With respect to summer habitat, we have determined that designating critical habitat would not be beneficial to the species. Further, with respect to wintering habitat, we have determined that the species is threatened by taking or human activity and identification of critical habitat could be expected to increase the degree of this threat to the species. An explanation of these determinations follows.

Designating Summer Habitat Would Not Be Beneficial to the Species

The northern long-eared bat is widely distributed throughout much of its range during the summer months and is considered to be flexible with regards to summer habitat requirements.

The best scientific information available on summer habitat suggests that where the northern long-eared bat is found, it is widely distributed in a variety of wooded habitats (ranging from highly fragmented forest habitats to contiguous forest blocks from the southern United States to Canada's Yukon Territory), with generally non-specific habitat elements. There are elements of summer habitat that the northern long-eared bat needs (forests for roosting, raising young, foraging, and commuting between roosting and foraging habitat); however, the best available information indicates that the species' specific needs and preferences for these habitat elements are relatively flexible, plentiful, and widely distributed. Thus, summer habitat for the northern long-eared bat does not have specific physical or biological features that are essential to the conservation of the species and, therefore, does not meet the definition of critical habitat.

Furthermore, as discussed in the final listing rule (80 FR 17974; April 2, 2015), northern long-eared bat summer habitat is not limited or in short supply, and summer habitat loss is not a rangewide threat to the species. Based on a compilation of the total forested acres for each State in the northern long-eared bat's range (from the U.S. Forest Service's 2015 State and Private Forestry Fact sheets (available at *http://stateforesters.org/regional-state*)), there are an estimated 281,528,709 acres (113,213,960 hectares) of available forested habitat for the northern long-eared bat throughout its range in the United States (Service 2016, p. 28). This is assuming that all forested acres are suitable for the northern long-eared bat, which probably overestimates habitat availability, but such an assumption is not unreasonable given the northern long-eared bat's flexible selection of summer habitat and ability to use very small trees (≥3 in (8 cm) in dbh) (Service 2016, p. 18).

As we documented in the final listing rule (80 FR 17974; April 2, 2015), the extent of conversion from forest to other land cover types has been fairly consistent with conversion to forest (cropland reversion/plantings). Further, the recent past and projected future amounts of forest loss to conversion was, and is anticipated to be, only a small percentage of the total amount of forest habitat. For example, the U.S. Forest Service expects only 4 to 8 percent of the forested area found in 2007 across the conterminous United States to be lost by 2060 (U.S. Forest Service 2012, p. 12). Additionally, as discussed above, the northern long-eared bat has been documented to use a wide variety of forest types across its wide range (living in highly fragmented forest habitats to contiguous forest blocks from the southern United States to Canada's Yukon Territory). Because summer habitat for the northern long-eared bat is not limiting, and because the northern long-eared bat is considered to be flexible with regards to summer habitat, the availability of forested habitat does not now, nor will it likely in the future, limit the conservation of the northern long-eared bat.

The critical habitat regulations at 50 CFR 424.12(a)(1)(ii) provide two examples of when designating critical habitat may not be beneficial to the species and, therefore, may be not prudent: Where the present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species, or where there are no areas that meet the definition of critical habitat for the species. The summer habitat for the northern long-eared bat falls within both examples. First, there are no areas of summer habitat that meet the definition of critical habitat for the northern long-eared bat. Second, the present or threatened destruction, modification, or curtailment of summer habitat is not a threat to the species; rather, disease is the primary threat to the species within its summer habitat. In the final rule revising the critical habitat regulations (81 FR 7414; February 11, 2016), the Services expressly identified this situation as an example where designating critical habitat may not be beneficial to the species: "In some circumstances, a species may be listed because of factors other than threats to its habitat or range, such as disease, and the species may be a habitat generalist. In such a case, on the basis of the existing and revised regulations, it is permissible to determine that critical habitat is not beneficial and, therefore, not prudent" (see 81 FR 7425; February 11, 2016). Therefore, we conclude that designating the summer habitat of the northern long-eared bat as critical habitat is not prudent.

Increased Threat to the Taxon by Designating Critical Habitat in Their Hibernacula

Disturbance of hibernating bats (as discussed under Factor A of the final listing rule (80 FR 17974, April 2, 2015; see 80 FR 17989–17990)) has long been considered a threat to cave-hibernating bat species, including the northern long-eared bat. Northern long-eared bats hibernate during the winter months to conserve energy from increased thermoregulatory demands and reduced food resources. To increase energy savings, individuals enter a state of torpor, when internal body temperatures approach ambient temperature, metabolic rates are significantly lowered, and immune function declines (Thomas *et al.* 1990, p. 475; Thomas and Geiser 1997, p. 585; Bouma *et al.* 2010, p. 623). Each time a bat arouses from torpor, it uses a significant amount of energy to warm its body and increase its metabolic rate. These arousals during hibernation cause the greatest amount of energy depletion in hibernating bats (Thomas *et al.* 1990, p. 477). The cost and number of arousals are the two key factors that determine energy expenditures of hibernating bats in winter (Thomas *et al.* 1990, p. 475). Human disturbance at hibernacula can cause bats to arouse more frequently, causing premature energy store depletion and starvation (Thomas 1995, p. 944; Speakman *et al.* 1991, p. 1103), leading to marked reductions in bat populations (Tuttle 1979, p. 3) and increased susceptibility to disease.

The primary forms of human disturbance to hibernating bats result from recreational caving, vandalism, cave commercialization (cave tours and other commercial uses of caves), and research-related activities (Service 2007, p. 80). Fire building is also a common form of disturbance that, in addition to elevating interior temperatures (which is detrimental during hibernation) and accumulating smoke, can deposit soot on ceilings and eventually result in site abandonment by bats (Tigner and Stukel 2003, p. 54). In addition to unintended effects of commercial and recreational caving, intentional killing of bats in caves by shooting, burning, and clubbing has been documented (Tuttle 1979, pp. 4, 8). Intentional killing of northern long-eared bats has been documented at a small percentage of hibernacula (*e.g.,* one case of shooting disturbance in Maryland, and one case of bat torching in Massachusetts where approximately 100 bats (northern long-eared bats and other species) were killed) (Service, unpublished data).

Prior to the outbreak of WNS, Amelon and Burhans (2006, p. 73) indicated that "the widespread recreational use of caves and indirect or direct disturbance by humans during the hibernation period pose the greatest known threat to this species (northern long-eared bat)." In addition, human disturbance at hibernacula has been identified by many States as the next greatest threat to the bat after WNS. Of 14 States that assessed the possibility of human disturbance at bat hibernacula within the range of the northern long-eared bat, 13 identified at least 1 known hibernacula as having been negatively affected by human disturbance (Service 2012, unpublished data). Eight of these 14 States (Arkansas, Kentucky, Maine, Minnesota, New Hampshire, North Carolina, South Carolina, and Vermont) indicated the potential for human disturbance at over 50 percent of the known hibernacula in that State. Nearly all States without WNS identified human disturbance as the primary threat to hibernating bats, and all others (including WNS-positive States) noted that human disturbance either is of significant concern or is the next greatest threat after WNS (Service 2012, unpublished data).

Since the time of listing (April 2, 2015), additional information has become available that demonstrates that designating critical habitat for the northern long-eared bat would likely increase the threat from vandalism and disturbance, and could, potentially, increase the spread of WNS. In November 2015, we sought information from State fish and wildlife agencies and other public landowners with known bat caves or mines to determine: (1) How prevalent accounts of disturbance to bats and vandalism to hibernacula are throughout the species' range; and (2) the level and types of concerns that State fish and wildlife agencies and other landowners with known bat caves or mines have regarding the release of known bat hibernacula location information.

Prevalence of Disturbance—State and other agency or organization personnel provided information regarding specific incidents of disturbance of hibernating bats within their State or area of jurisdiction. Incidents were reported throughout the range of the northern long-eared bat. Evidence of vandalism of caves and mines and disturbance of bats included: dead bats, graffiti, trash, evidence of camp fires, bottle rockets, fireworks, digging or excavation, attempts to remove rock or minerals, alteration of cave or mine entrances, and damage to and breach of gates. There were also a few reported incidents of intentional killing of bats, including clubbing, thrown rocks, and burning. In addition, materials found in hibernacula, such as tennis rackets and blow torches, indicate harm inflicted on bats (NJDFW 2015, pers. comm.). There are few law enforcement reports regarding these incidents, either due to a lack of law enforcement actions or because reporting these incidents would publicize mine or cave locations (SCDNR 2015, pers. comm.).

Examples of incidents of vandalism and disturbance to bats at publicly known hibernacula have been found throughout the range of the northern long-eared bat; we received examples of vandalism and disturbance to bats from 20 State fish and wildlife agencies and 9 other public landowners (including Federal, State, and local agencies and organizations) with known northern long-eared bat hibernacula. Due to the large number of specific incidents, a small, representative subset of the examples we received is presented below. For purposes of illustrating that these incidents occur throughout the species' range, the information is organized into four geographic areas: Northeast, southeast, midwest, and west.

Northeast: In northeastern States such as Pennsylvania and New York, vandalism and disturbance to bats within hibernacula occurs frequently. Evidence of human use of caves and mines in Pennsylvania, including digging for new passage, waste, all-terrain-vehicle use, guns being shot, and burning, are common. There are also many examples of people trying to cut, remove, or get around gates to access gated hibernacula (PGFC 2015, pers. comm.). Due to the large numbers of people trespassing in Pennsylvania caves and mines, especially during winter months while bats are hibernating, the Pennsylvania Game Commission installed cameras at many caves to capture visual proof of those illegally entering caves and send automated messages to alert a wildlife conservation officer of the entry. Since January 2015, conservation officers have confronted at least 50 suspected trespassers, resulting in more than 20 citations (PGFC 2015, pers. comm.). Similarly, in New York, nearly all ungated hibernacula, both on public and private lands, are visited by people, and many gated caves and mines have been compromised. Some sites have signs informing visitors that caves and mines are closed to visitation in the winter; however, this does not stop individuals from accessing those sites (NYDEC 2015, pers. comm.).

Southeast: In southeastern States such as South Carolina, North Carolina, and Kentucky, vandalism and disturbance to bats within hibernacula occurs often. For example, in South Carolina reports exist of bottle rockets being shot into a gated mine, missing locks on bat-friendly gates, litter inside a cave, and individuals barricading an entrance to a cave (SCDNR 2015, pers. comm.). In North Carolina, there are multiple incidents of vandalism to caves and mines. One particular mine in North Carolina has had repeated vandalism issues over several years, and multiple security fences, gates, and locks have been compromised by vandalism (NCWRC 2015, pers. comm.). In Kentucky, 82 of 118 total hibernacula where northern long-eared bats have been observed are exposed to human disturbance; in 2007, two people were convicted of intentionally killing more than 100 federally-listed Indiana bats in a Kentucky cave (USFWS 2010).

Midwest: There are multiple records of vandalism and disturbance of bats in Midwestern States, including Michigan, Indiana, Wisconsin, Missouri, and Minnesota. The first mine to have WNS-associated bat mortality in Michigan had been illegally accessed in 2013, when people used a torch to break the gate. The WNS-associated mortality was "likely as a direct result of this disturbance" (MIDNR 2015, pers. comm.). Winter visitation to caves in Indiana is relatively common, and in one particular incident, hibernating Indiana bats were intentionally burned (INDNR 2015, pers. comm.). In Wisconsin, five State-owned underground sites were sealed for use if there was a need for artificial hibernacula for WNS treatment trials; all five were breached (welded doors were ground off) during the spring of 2015. Additionally, one private landowner filled in a cave on their property when they learned it was occupied by bats (WDNR 2015, pers. comm.). In Missouri, there has been evidence of digging at cave entrances, parties, fires, fireworks, graffiti, off-highway vehicle use, gate damage, and trash left behind at caves throughout the State. In fact, there is an ongoing investigation and prosecution regarding illegal entry at a Missouri cave (MDC 2016, pers. comm.). Issues with breached gates and broken locks occurred at several Minnesota caves; approximately 4 years ago, surveyors found bat bones and shotgun shells in one cave.

West: In States such as South Dakota, Arkansas, and Oklahoma in the western portion of the northern long-eared bat's range, there are several records of incidents of vandalism and disturbance to bats as well. The South Dakota Department of Game, Fish, and Parks provided literature with evidence of both historical and ongoing vandalism at their State's hibernacula. Increasing disturbance of known hibernacula throughout the Black Hills area is noted as one of the greatest threats to bat populations in the area (Tigner and Stukel 2003, p. 11). Some of the more disruptive and damaging activities inside caves and abandoned mines include discharging firearms and fireworks, spray-painting, campfire construction, and intentionally killing bats and other wildlife (Tigner and Stukel 2003, p. 54). At one particular cave, campfires are common during hibernation, and only a small fraction of the bats identified in the cave in the early 1990s still use the cave (Tigner 2002, p. 7). In Arkansas, approximately 200 endangered gray bats (*Myotis grisescens*) were killed at a major gray bat hibernaculum on National Park Service land (AGFC 2015, pers. comm.). In Oklahoma, there have been multiple incidents involving cutting fences around gate entrances, breaching cave gates (by cutting, digging under, or removing structures around gates to gain access), and campfires near cave entrances (Service 2015, pers. comm.).

Summary: As illustrated by the examples above, which are only a small subset of the reported incidents, we have extensive rangewide evidence that indicates known northern long-eared bat hibernacula have been, and are likely to continue to be, disturbed and vandalized. These acts not only lead to increases in disturbance during the northern long-eared bat's sensitive hibernation period, which, in turn, leads to decreased survival, but also may lead to direct mortality of northern long-eared bats.

Concerns over Release of Location Information—Northern long-eared bats that are infected with WNS are believed to be less resilient to disturbance and resulting arousal, and the northern long-eared bat is one of the most highly susceptible bat species to WNS (Langwig *et al.* 2014). As discussed in the final listing rule (80 FR 17974, April 2, 2015; see 80 FR 17993–17998), WNS-causing fungal spores can be transmitted not only by bat-to-bat transmission, but also by human actions (USGS National Wildlife Health Center, Wildlife Health Bulletin 2011–05), and decontamination remains one of the only management options available to reduce the risk of human-assisted transmission. State, Federal, and local agencies and organizations are especially concerned with the spread of WNS if cave and mine locations are made public, especially in sites where WNS has not been found or in areas that have not yet been inundated with the disease. Several agency and organization personnel expressed concern regarding those visiting caves and mines and not properly decontaminating after leaving hibernacula, which may result in these visitors spreading WNS fungal spores by using contaminated gear in uninfected caves or mines (ANHC 2015, pers. comm.; CDEEP 2015, pers. comm.; KDFWR 2015, pers. comm.; NBSRP 2015, pers. comm.; NJDVW 2015, pers. comm.; WDNR 2015, pers. comm.; WGFD 2015, pers. comm.). It is possible that the spread of WNS was enhanced by human transfer of fungal spores in some States, such as Connecticut (CDEEP 2015, pers. comm.).

State, Federal, and local agencies that gather specific location information exercise extra efforts to protect hibernacula location information from becoming readily available to the public. In fact, many States reported that they are concerned that release of location information could significantly increase human visitation, thereby increasing disturbance to bats, and, therefore, they do not share hibernacula location information with the public. For example, the Wisconsin Department of Natural Resources stated, "we have not shared locational information as to maternity sites and hibernacula. Under state law, locations deemed critical to the survival of the species may be withheld from the public. All data in the WI Natural Heritage Inventory are exempt from State open records laws" (WDNR 2015, pers. comm.). Some agencies and organizations state that when location information is disclosed, an agreement typically must be in place with those requesting the location information to protect the data, and point data are buffered to conceal the specific locations. Similarly, in Missouri, the Missouri Department of Conservation (MDC) does not release hibernacula locations to the general public, and location information for caves not owned by MDC cannot be disclosed by the State (MDC 2016, pers. comm.).

In addition to protecting location information, State, Federal, and local agencies and organizations use other means to protect bat hibernacula, such as installation of bat-friendly gates. Direct protection of caves and mines can be accomplished through installation of bat-friendly gates that allow passage of bats while reducing disturbance from human entry as well as reducing changes to the cave microclimate from air restrictions. Bat-friendly gates are generally thought to be effective in preventing disturbance of hibernating bats and vandalism of hibernacula (AGFC 2015, pers. comm.; ANF 2015, pers. comm.; ANHC 2015, pers. comm.; BNR 2015, pers. comm.; CDEEP 2015, pers. comm.; DMCC 2015, pers. comm.; IADNR 2015, pers. comm.; ILDNR 2015, pers. comm.; INDNR 2015, pers. comm.; KDFWR 2015, pers. comm.; MANG 2015, pers. comm.; MDC 2016, pers. comm.; MIDNR 2015, pers. comm.; NBSRP 2015, pers. comm.; NGDFW 2015, pers. comm.; NYDEC 2015, pers. comm.; ONF 2015, pers. comm.; ONSR 2015, pers. comm.; OSFNF 2015, pers. comm.; PGC 2015, pers. comm.; SCDNR 2015, pers. comm.; SDGFP 2015, pers. comm.; SMP 2015, pers. comm.; WDNR 2015, pers. comm.), although attempts to protect hibernacula from disturbance have varying degrees of effectiveness. In most States for which we have information, a small percentage of caves and mines are gated, and a majority of State agencies indicated that there is a need to gate additional caves and mines used by bats. For example, in Missouri, less than approximately 2 percent of known hibernacula have bat-friendly gates Statewide (MDC 2015, pers. comm.). Attempts to remove gates at hibernacula are numerous and pervasive throughout the northern long-eared bat's range, although the success of removal attempts varies. Some State and Federal agencies and other organizations state that attempts to remove gates are rarely successful; others, such as the Kentucky Department of Fish and Wildlife Resources, state that removal attempts are almost always successful: "When parties wish to gain access, they are very resourceful and come prepared to cut, dig, pry, or use any other means necessary to enter. The remote nature of some sites does not seem to deter vandalism either" (KDFWR 2015, pers. comm.). See *Prevalence of Disturbance,* above, for more examples of attempts to remove gates.

The process of designating critical habitat would increase human threats to the northern long-eared bat by increasing the vulnerability of this species to disturbance during its sensitive hibernation period and by increasing the likelihood of vandalism to its winter hibernacula by publicly disclosing the locations of those hibernacula. Northern long-eared bats are particularly sensitive to disturbance while hibernating, and such disturbance further reduces survival chances of already compromised, WNS-infected bats. Additionally, increased human access to hibernacula may facilitate or accelerate the spread of WNS to uninfected sites, as people may carry the fungal spores from site to site. Designation of critical habitat requires the publication of maps and a specific narrative description of critical habitat in the **Federal Register**. The degree of detail in those maps and boundary descriptions is far greater than the general location information provided in the final listing rule (80 FR 17974; April 2, 2015). Furthermore, a critical habitat designation normally results in the news media publishing articles in local newspapers and on special interest Web sites, usually with maps of the critical habitat. We have determined that the publication of maps and descriptions outlining the locations of this species' wintering areas would increase awareness and visitation of hibernacula, and thus disturbance of bats, as those interested in accessing caves and mines would then have detailed location information for these hibernacula. As expressed by many State bat biologists and land managers with hibernacula within their area of jurisdiction, there is a strong concern regarding publicizing cave and mine location information due to the increased threat of disturbance to the northern long-eared bat, and bats in general. Furthermore, human disturbance may exacerbate the effect of WNS on northern long-eared bats; providing a literal map of bat hibernacula in the form of critical habitat will likely facilitate human disturbance and may further compound threats to the species. We, therefore, conclude that the northern long-eared bat is threatened by taking and other human activity, and identification of critical habitat can be expected to increase the degree of threat to the species. Designating critical habitat is therefore not prudent under the regulations at 50 CFR 424.12(a)(1)(i). As discussed earlier, the risk of increased threats from publishing hibernacula locations is significant. The northern long-eared bat, and bats in general, are very sensitive to disturbance while hibernating, and there are numerous known incidents of vandalism, targeted killing, and disturbance of hibernating northern long-eared bats throughout the species' range. The public has great interest in visiting caves and mines for recreational purposes, and human-caused disturbance has clear effects on hibernating bats. Thus, any action that publicly discloses the location of northern long-eared bat hibernacula (such as a critical habitat designation) puts the species in further peril. One of the basic measures to protect northern long-eared bats from vandalism and disturbance while hibernating is restricting access to information pertaining to the location of the species' hibernacula. Publishing maps and narrative descriptions of northern long-eared bat critical habitat would significantly affect our ability to reduce the threat of vandalism and disturbance of hibernacula and hibernating bats and may facilitate or intensify the spread of WNS by humans.

Summary of Prudency Determination

We have determined that designating critical habitat for the northern long-eared bat is not prudent. Designating summer habitat as critical habitat is not beneficial to the species, because there are no areas within the summer habitat of the species that meet the definition of critical habitat. Further, the primary threat to the species is the disease WNS; the destruction, modification, or curtailment of summer habitat is not a threat to the species as suitable summer habitat continues to exist and is not limited throughout the species' range. Therefore, designating critical habitat in the summer habitat areas would not be beneficial. Moreover, designating winter habitat as critical habitat would disclose hibernacula location information, and thereby increase the threat to the northern long-eared bat from vandalism and disturbance at hibernacula and could, potentially, increase the spread of WNS. Disturbance of hibernating bats has long been considered a threat to cave-hibernating bat species, and has been identified as the next greatest threat to this taxon after WNS. Human disturbance at hibernacula causes bats to arouse more frequently, leading to premature energy store depletion and, possibly, starvation. Further compounding the effects of disturbance, northern long-eared bats that are infected with WNS are believed to be less resilient to disturbance and resulting arousal. Furthermore, increased human visitation of hibernacula could intensify the spread of WNS from infected to uninfected sites. We have, therefore, determined in accordance with 50 CFR 424.12(a)(1) that it is not prudent to designate critical habitat for the northern long-eared bat.

References Cited

A complete list of references cited in this document is available on the Internet at *http://www.regulations.gov* and upon request from the Twin Cities Ecological Services Office (see **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this document are the staff members of the Twin Cities Ecological Services Office.

Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: April 12, 2016.

Michael J. Bean,

Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2016–09673 Filed 4–26–16; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 150903814–5999–02]

RIN 0648–XE564

Fisheries of the Northeastern United States; Summer Flounder Fishery; Quota Transfer

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; quota transfer.

SUMMARY: NMFS announces that the Commonwealth of Virginia is transferring a portion of its 2016 commercial summer flounder quota to the Commonwealth of Massachusetts. These quota adjustments are necessary to comply with the Summer Flounder, Scup and Black Sea Bass Fishery Management Plan quota transfer provision. This announcement informs the public of the revised commercial quotas for Virginia and Massachusetts.

DATES: Effective April 26, 2016, through December 31, 2016.

FOR FURTHER INFORMATION CONTACT: Elizabeth Scheimer, Fishery Management Specialist, (978) 281–9236.

SUPPLEMENTARY INFORMATION: Regulations governing the summer flounder fishery are found in 50 CFR 648.100 through 648.110. The regulations require annual specification of a commercial quota that is apportioned among the coastal states from Maine through North Carolina. The process to set the annual commercial quota and the percent allocated to each state are described in § 648.102.

The final rule implementing Amendment 5 to the Summer Flounder Fishery Management Plan, as published in the **Federal Register** on December 17, 1993 (58 FR 65936), provided a mechanism for transferring summer flounder commercial quota from one state to another. Two or more states, under mutual agreement and with the concurrence of the NMFS Greater Atlantic Regional Administrator, can transfer or combine summer flounder commercial quota under § 648.102(c)(2). The Regional Administrator is required to consider the criteria in § 648.102(c)(2)(i)(A) through (C) in the evaluation of requests for quota transfers or combinations.

Virginia is transferring 6,525 lb (2,959 kg) of summer flounder commercial quota to Massachusetts. This transfer was requested by Virginia to repay landings by a Virginia-permitted vessel that landed in Massachusetts under a safe harbor agreement.

The revised summer flounder quotas for calendar year 2016 are now: Virginia, 1,755,829 lb (796,430 kg); and Massachusetts, 577,777 lb (262,075 kg) based on the initial quotas published in the 2016–2018 Summer Flounder, Scup and Black Sea Bass Specifications, (December 28, 2015, 80 FR 80689) and previous 2016 quota transfers (March 8, 2016, 81 FR 12030 and April 14, 2016, 81 FR 22032).

Classification

This action is taken under 50 CFR part 648 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: April 21, 2016.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016–09726 Filed 4–26–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 150817730–6320–02]

RIN 0648–BF29

Fisheries of the Exclusive Economic Zone Off Alaska; Bering Sea and Aleutian Islands Management Area; American Fisheries Act; Amendment 111

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS issues this final rule to implement Amendment 111 to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP). This final rule reduces bycatch limits, also known as prohibited species catch (PSC) limits, for Pacific halibut in the Bering Sea and Aleutian Islands (BSAI) groundfish fisheries by specific amounts in four groundfish sectors: The Amendment 80 sector (non-pollock trawl catcher/processors); the BSAI trawl limited access sector (all non-Amendment 80 trawl fishery participants); the non-trawl sector (primarily hook-and-line catcher/processors); and the Western Alaska Community Development Quota Program (CDQ Program). This final rule establishes the following halibut PSC limits: 1,745 mt for the Amendment 80 sector; 745 mt for the BSAI trawl limited access sector; 710 mt for the BSAI non-trawl sector; and 315 mt for the CDQ Program. This results in an overall BSAI halibut PSC limit of 3,515 mt. This action is necessary to minimize halibut bycatch in the BSAI groundfish fisheries to the extent practicable and to achieve, on a continuing basis, optimum yield from the BSAI groundfish fisheries. This action is intended to promote the goals and objectives of the Magnuson-Stevens Fishery Conservation and Management Act, the FMP, and other applicable laws.

DATES: Effective May 27, 2016.

ADDRESSES: Electronic copies of the Environmental Assessment (EA), Regulatory Impact Review (RIR), and Finding of No Significant Impact (FONSI) prepared for this action, collectively "the Analysis;" the FMP; and the proposed rule are available from *http://www.regulations.gov* or from the

NMFS Alaska Region Web site at *http://alaskafisheries.noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Rachel Baker or Mary Alice McKeen, 907–586–7228.

SUPPLEMENTARY INFORMATION:

Background

NMFS manages the groundfish fisheries in the Exclusive Economic Zone (EEZ) of the BSAI under the FMP. The North Pacific Fishery Management Council (Council) prepared, and the Secretary of Commerce (Secretary) approved, the FMP pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) and other applicable laws. Regulations implementing the FMP appear at 50 CFR part 679. General regulations that pertain to U.S. fisheries appear at 50 CFR part 600. NMFS manages fishing for Pacific halibut through regulations established under the authority of the Northern Pacific Halibut Act of 1982.

NMFS published the Notice of Availability for Amendment 111 on October 29, 2015 (80 FR 66486) with comments invited through December 28, 2015. NMFS published the proposed rule to implement Amendment 111 on November 16, 2015 (80 FR 71650) with comments invited through December 16, 2015. The Secretary approved Amendment 111 on January 20, 2016. NMFS received 39 unique comments on the FMP and proposed rule from 17 different commenters. A summary of these comments and the responses by NMFS are provided under the heading Response to Comments below. These comments did not result in any change to the proposed rule.

A detailed review of the provisions of Amendment 111, the proposed regulations to implement Amendment 111, and the rationale for these regulations is provided in the preamble to the proposed rule (80 FR 71650, November 16, 2015) and is not repeated here (see **ADDRESSES**). The preamble to this final rule provides a brief review of the regulatory changes made by this final rule. In this preamble, unless otherwise noted, the citations to regulations are to the regulations that will be in place after the effective date of this final rule.

NMFS manages halibut PSC, also known commonly as halibut bycatch, in groundfish fisheries under the authority of the Magnuson-Stevens Act. Under Section 3.6.1 of the FMP, and the implementing regulation at § 679.21(a)(2), prohibited species are Pacific halibut, Pacific herring, Pacific salmon and steelhead, king crab, and Tanner crab. Under the FMP and the regulations, prohibited species must be avoided while fishing for groundfish and must be returned to the sea with a minimum of injury except where retention is required or authorized by law.

Under the Magnuson-Stevens Act, bycatch includes fish that are discarded for any reason, including discards required by regulation, or for economic reasons, such as the fact that the fish might be of an undesirable size, sex, or quality (16 U.S.C. 1802 (3); 16 U.S.C. 1802 (9)). Halibut PSC is one type of bycatch; it is a regulatory discard. Regulations at § 679.21(a)(2) require the discard of all halibut that is caught while directed fishing for groundfish in the BSAI or the Gulf of Alaska. A limited exception to this discard requirement is provided for donations of halibut made under the prohibited species donation program authorized in regulation at § 679.26. In this preamble, when NMFS refers to halibut bycatch, NMFS means halibut PSC.

Pacific halibut (*Hippoglossus stenolepis*) is fully utilized in the waters off Alaska as a target species in subsistence, personal use, recreational (sport), and commercial halibut fisheries. Halibut is also incidentally taken as bycatch in groundfish fisheries. Although participants in the groundfish fisheries are under an obligation to avoid halibut, all halibut cannot be avoided. The groundfish fisheries cannot be prosecuted without some amount of halibut bycatch because groundfish and halibut occur in the same areas at the same times and because no fishing gear or technique has been developed that can avoid all halibut bycatch.

Although halibut is taken as bycatch by vessels using all types of gear (trawl, hook-and-line, pot, and jig gear), halibut bycatch primarily occurs in the trawl and hook-and-line groundfish fisheries. Halibut bycatch occurs in both the Gulf of Alaska and the BSAI. The greatest portion of halibut bycatch occurs in the BSAI. NMFS manages halibut bycatch in the BSAI groundfish fisheries by (1) establishing halibut PSC limits for trawl and non-trawl fisheries; (2) apportioning those halibut PSC limits to groundfish sectors, fishery categories, and seasons; and (3) managing groundfish fisheries to prevent halibut PSC use from exceeding the established limits. The proposed rule contains a detailed explanation of halibut bycatch management in the BSAI groundfish fisheries (80 FR 71650, 71654–71660, November 16, 2015).

Consistent with National Standard 1 and National Standard 9 of the Magnuson-Stevens Act, the Council and NMFS use halibut PSC limits in the BSAI groundfish fisheries to minimize bycatch to the extent practicable as required by National Standard 9, while achieving, on a continuing basis, optimum yield from the groundfish fisheries as required by National Standard 1. With one limited exception, groundfish fishing is prohibited once a halibut PSC limit has been reached for a particular sector, fishery, or season, depending on the particular halibut PSC limit. The limited exception is that groundfish fishing in the pollock/Atka mackerel/"other species" trawl fishery is not prohibited if that fishery reaches its halibut PSC limit. (80 FR 71650, 71658, November 16, 2015). Although there is no formal regulatory constraint, this fishery (pollock/Atka mackerel/"other species") has not exceeded its halibut PSC limit in recent years (*i.e.,* 2013, 2014 and 2015).

The use of halibut PSC limits in the groundfish fisheries reduces halibut bycatch and promotes conservation of the halibut resource. Halibut bycatch in the groundfish fisheries may affect commercial, sport, and subsistence halibut fishing opportunities by decreasing the amount of halibut available for those fisheries. Therefore, the Council and NMFS establish halibut PSC limits to balance the needs of fishermen, fishing communities, and U.S. consumers that consume halibut and groundfish.

Actions Implemented by This Rule

This final rule changes the halibut PSC limits for BSAI groundfish fisheries. This table shows the current halibut PSC limits and the halibut PSC limits that will be in effect with this final rule.

BSAI Groundfish fisheries—sectors	Description of sector	Previous halibut PSC limit (mt)	Halibut PSC limit established under this final rule (mt)	Percentage decrease from the previous halibut PSC limit
1. Amendment 80	Non-pollock trawl catcher/processors	2,325	1,745	25
2. BSAI trawl limited access	All other trawl catcher/processors	875	745	15
3. BSAI non-trawl	Primarily hook-and-line catcher/processors	833	710	15
4. CDQ Program	Vessels fishing for CDQ groups	393	315	20
Overall BSAI limit		4,426	3,515	21

PSC limits are stated in metric tons of halibut mortality.
CDQ Program = Western Alaska Community Development Quota Program.

With one exception, this final rule does not change the complex process for apportioning halibut PSC limits among sectors, fisheries, and seasons (see regulations at § 679.21(b)). The exception is that this final rule makes a single process change to halibut PSC apportionment for the CDQ Program. Under current regulations, the allocation of halibut PSC to the CDQ Program is made as a Prohibited Species Quota Reserve (PSQ Reserve) that is derived partly from the halibut PSC limit established for the trawl fisheries and partly from the halibut PSC limit for the non-trawl fisheries. This final rule establishes a separate halibut PSC limit for the CDQ Program. The halibut PSC limit for the CDQ Program will be established specifically in regulation, and will no longer be derived from the halibut PSC limit established for the trawl and non-trawl fisheries.

For a full description of the apportionment of halibut PSC among the BSAI groundfish fisheries, see the section in the preamble to the proposed rule, "Halibut Bycatch Management in the BSAI Groundfish Fisheries" (80 FR 71650, 71655–71656, November 16, 2015).

Summary of Regulatory Changes

This final rule makes the following changes to regulations at 50 CFR part 679:

- Moves the general provisions on prohibited species bycatch management from § 679.21(b) to § 679.21(a).
- Moves all the provisions on BSAI halibut bycatch management in current § 679.21(e) to a new § 679.21(b) and reorganizes the provisions in the new § 679.21(b) to improve clarity.
- Establishes new BSAI halibut PSC limits in § 679.21(b): 1,745 mt for the Amendment 80 sector; 745 mt for the BSAI trawl limited access sector; 710 mt for the BSAI non-trawl sector; and 315 mt for the CDQ Program.
- Uses the term "PSC allowance" rather than "bycatch allowance" in § 679.21(b) and uses the term "PSC" rather than "incidental catch" in § 679.21(b)(1)(ii)(C).
- Changes cross-references from § 679.21(e) to § 679.21(b) where necessary.
- Changes the BSAI halibut PSC limits in Table 35 and Table 40 to the new limits.

Changes From the Proposed Rule

This final rule does not change any of the regulations as proposed in the proposed rule (80 FR 71650, November 16, 2015).

Response to Comments

NMFS received 39 unique comments on the proposed rule or Amendment 111 from 17 commenters. The 17 commenters consisted of six individuals; three fishing industry groups, one of which represents Amendment 80 participants, one of which represents hook-and-line catcher/processors, one of which represents predominantly hook-and-line catcher vessels; three Alaska Native Tribal Organizations; one Alaska Native Village Corporation; one non-profit corporation engaged in commercial fishing; one for-profit corporation engaged in wilderness marine tours; one conservation organization; and one anonymous comment.

Of the 17 commenters, 14 explicitly supported adoption of the proposed halibut PSC reductions. Most of these commenters (12 out of 14) favored larger halibut PSC limit reductions. The comment from the corporation engaged in wilderness tours was the only comment that recommended that the Secretary disapprove Amendment 111. The comment from the Amendment 80 fishing industry group questioned whether the proposed halibut PSC limit reductions were practicable but did not recommend disapproval of Amendment 111 or rejection of the proposed rule.

In responding to these comments, when NMFS refers to Amendment 111, unless otherwise noted, NMFS means Amendment 111 and this final rule implementing Amendment 111. There were no public comments asserting that the proposed rule is not consistent with Amendment 111, and NMFS did not make any changes from the proposed to this final rule. Therefore, NMFS' responses to comments on Amendment 111 also apply to the proposed and final rules.

Comments Related to the Magnuson-Stevens Act and National Standards Generally

Comment 1: Amendment 111 should be approved and implemented.

Response: The Secretary, through his designee, the Assistant Administrator for Fisheries, approved Amendment 111 on January 20, 2016, and implements Amendment 111 with this final rule. The Secretary concluded that the PSC limit reductions in Amendment 111 are consistent with the Magnuson-Stevens Act including the national standards and other applicable law.

Comment 2: Twelve commenters stated they were in favor of the Secretary approving Amendment 111 but would have preferred larger reductions in the PSC limits. Some of these commenters stated that Amendment 111 was a "first step," was "a step in the right direction," and was "a positive action," to reducing BSAI halibut bycatch.

Response: Before the Council recommended Amendment 111 for approval and implementation by the Secretary, the Council reviewed an extensive record that included the Analysis, input from Council and NMFS staff, and extensive public testimony. The Council considered a broad range of potential halibut PSC limit reductions, and recommended Amendment 111 only after considering halibut PSC limit reductions that ranged from 10 to 50 percent lower than the current halibut PSC limits in each BSAI groundfish sector. The Council recommended halibut PSC limit reductions within the range of the alternatives considered.

The Council concluded, and the Secretary agreed, that Amendment 111 is consistent with all national standards, and specifically the directive in National Standard 9 to minimize halibut PSC to the extent practicable while preserving the potential for the harvest of optimum yield in the BSAI fisheries consistent with National Standard 1. The Council also concluded, and the Secretary agreed, that Amendment 111 would take into account the effect of halibut PSC limit reductions on communities dependent on the groundfish fisheries and communities dependent on the halibut fishery consistent with National Standard 8. The Council concluded, and NMFS agrees, that the PSC limits reductions in Amendment 111 met the purpose and need for this action, namely to minimize bycatch to the extent practicable while preserving the potential for optimum yield from the groundfish fisheries. (Section 1.2 of Analysis) The rationale for rejecting larger PSC reductions in each sector is explained in the proposed rule (80 FR 71650, 71663—71668, November 16, 2015) and is summarized in the response to Comment 14.

Comment 3: NMFS should adopt the BSAI halibut PSC limits in Amendment 111 by implementing a final rule with those reductions. However, NMFS should reject the part of the proposed rule that asserts that the proposed rule complies with the Magnuson-Stevens Act because Amendment 111 does not represent a proper balancing of the national standards in the Magnuson-Stevens Act.

Response: As explained in response to Comments 1 and 2, the Secretary determined that Amendment 111 is consistent with the national standards and other applicable law and approved Amendment 111 on January 20, 2016.

Comment 4: The Secretary should disapprove Amendment 111, withdraw the proposed rule, and instruct the Council to expedite the preparation of a new FMP amendment that recommends larger halibut PSC limit reductions.

Response: As explained in response to Comments 1 and 2, the Secretary has determined that Amendment 111 is consistent with the national standards and other applicable law and approved Amendment 111 on January 20, 2016. The Council recommended Amendment 111 after considering halibut PSC limit reductions that were 10 to 50 percent lower than the current halibut PSC limits in each BSAI groundfish sector. The Council concluded that larger reductions are not practicable and would reduce the net benefit to the nation. The rationale the Council and NMFS used for concluding that larger reductions in PSC limits are not practicable is described in the preamble to the proposed rule. (80 FR 71650, 71663–71668, November 16, 2015). See also responses to Comments 2 and 14.

Comment 5: The proposed rule concluded that the halibut PSC limit reductions for the Amendment 80 sector would provide the greatest benefit to the nation. (80 FR 71650, 71664, November 16, 2015) In reaching this conclusion, NMFS did not consider the high value of the halibut fishery and resource.

Response: NMFS agrees that halibut has a high socioeconomic value but disagrees that the Analysis for this action did not take that into account. The Analysis contains numerous sections that describe the value of the commercial halibut fishery and summarize the potential impact of halibut PSC reductions ranging from 10 to 50 percent lower than the current halibut PSC limits in each sector (see Sections 4, 5 and Appendix D in the Analysis). For each level of halibut PSC limit reduction analyzed, the Analysis evaluated possible benefits to the directed halibut fishery by looking at the estimated increase in wholesale revenues in the directed halibut fishery that would occur from each level of reduction. The wholesale revenues in the directed halibut fishery are based on the estimated price per pound for halibut sold (see, *e.g.,* Table ES–4 and ES–5 in the Analysis).

The Analysis also looked at the socioeconomic value of halibut among the various communities that participate in the halibut fisheries. Section 4.5.3 and Appendix C of the Analysis described the socioeconomic impacts of the alternatives analyzed by the Council before it selected a preferred alternative. Appendix C looked at various metrics to measure the value of the directed halibut fisheries to communities including vessel ownership related to the directed commercial halibut fishery and employment related to the directed commercial halibut fishery. Appendix C also evaluated the value of halibut, and the potential impacts from the action alternatives, on the subsistence fisheries, and Section 3.1.4.3 assessed the potential impact of Amendment 111 on sport halibut fisheries.

Comment 6: NMFS should take, or commit to taking, the following additional actions to reduce halibut bycatch: Additional reductions in the halibut PSC limits; modifications to the process for annual groundfish total allowable catch (TAC) allocations to better incorporate concerns about halibut bycatch; adopting an abundance-based management for halibut so that PSC limits in some way automatically decrease when halibut is scarce and automatically increase when halibut is abundant; adopting a performance standard for halibut PSC management by the Amendment 80 sector; mandating deck sorting to ensure halibut are returned to sea as soon as possible to reduce the mortality of halibut bycatch; limiting the reallocation of halibut PSC from the BSAI trawl limited access sector to the Amendment 80 sector so that unused halibut PSC in the BSAI trawl limited access sector is not fully used; and adopting area closures for the BSAI groundfish fisheries on a seasonal basis to reduce the potential impacts of groundfish fisheries on halibut habitat.

Response: The actions suggested by the commenters are outside the scope of this final rule. NMFS notes that the Council and NMFS, in conjunction with the IPHC, are considering a range of actions to improve the management of halibut PSC. Several of the actions suggested by the commenter are under consideration. A partial list of actions underway or under consideration follows:

- A joint meeting to promote a more collaborative approach to halibut management in February 2015;
- The development of a halibut framework document to further the objective to balance the needs of directed halibut users and halibut bycatch users in the BSAI and Gulf of Alaska. This framework document will be reviewed by the Council in April 2016;
- The establishment of a work group comprised of Council, NMFS, and IPHC staff to evaluate linking halibut PSC limits to a metric or metrics of halibut abundance in December 2015;
- Beginning in December 2015, annual reporting by Amendment 80 cooperatives describing their ongoing efforts to avoid halibut bycatch to ensure halibut PSC use is below the halibut PSC limits that would be established for the Amendment 80 cooperatives under this final rule; and
- NMFS' approval of an expedited exempted fishing permit in 2015 to evaluate halibut deck sorting as a means to reduce halibut bycatch mortalities (Appendix A–7 of the Analysis). NMFS is currently processing an application for an additional exempted fishing permit to test halibut deck sorting methods for 2016.

For a more complete description of the range of actions being considered by the Council, IPHC, and NMFS to address halibut bycatch management, please see the newsletters on the Council's Web site: *http://www.npfmc.org/npfmc-newsletters/.*

Comments Associated With Specific National Standards

Comment 7: Under National Standard 1, an FMP should prevent overfishing while achieving, on a sustainable basis, the "optimum yield" from a fishery. The definition of optimum yield in the Magnuson-Stevens Act states that the optimum yield is the amount of fish that "will provide the greatest overall benefit to the Nation, particularly with respect to food production and recreational opportunities, and taking into account the protection of marine ecosystems." (16 U.S.C. 1802(33)) Halibut bycatch is preventing the directed halibut fishery from achieving optimum yield.

Response: Halibut does not have an "optimum yield" within the Magnuson-Stevens Act definition because halibut is not managed pursuant to the Magnuson-Stevens Act. Halibut is managed under the Convention between the United States and Canada for the Preservation of the Halibut Fishery of the North Pacific Ocean and Bering Sea (Convention), signed at Ottawa, Ontario, on March 2, 1953, as amended by a Protocol Amending the Convention (signed at Washington, DC on March 29, 1979). The Convention is implemented in the U.S. by the Northern Pacific Halibut Act of 1982 (Halibut Act). Therefore halibut bycatch is not preventing the achieving of optimum yield in the directed halibut fishery because halibut does not have an "optimum yield" established under the Magnuson-Stevens Act.

Pursuant to the Convention, the International Pacific Halibut Commission (IPHC) makes stock assessment and catch limit decisions for halibut. Although the IPHC does not establish an "optimum yield" for halibut, the IPHC harvest policy includes a harvest control rule that reduces commercial harvest rates linearly if the stock is estimated to have fallen below established thresholds for female spawning biomass. These harvest control rules would severely curtail the commercial halibut fishery during times of particularly poor stock conditions. The current status of the halibut stock has not triggered the application of the IPHC's restrictive harvest control rules. (Proposed Rule, 80 FR 71650, 71652, November 16, 2015). Even without any reduction in halibut PSC limits, the halibut stock is stable or potentially increasing slightly in overall abundance, as measured by the IPHC stock assessment of exploitable halibut biomass and female spawning biomass. (Section 3.1.1 of the Analysis; 80 FR 71650, 71651, November 16, 2015).

Amendment 111 does, however, seek to reduce halibut bycatch in the BSAI groundfish fisheries to the extent practicable as required by National Standard 9. If halibut bycatch is decreased, there will be more halibut available for the IPHC to allocate to the directed halibut fisheries: Commercial, sport and subsistence. NMFS therefore expects that this action will decrease halibut PSC use and will make more halibut available for the directed halibut fisheries.

Comment 8: Amendment 111 does not properly balance National Standard 1 and National Standard 9. NMFS has described the purpose of the amendment as limiting "the use of PSC limits to minimize halibut bycatch in the groundfish fisheries, to the extent practicable, while achieving, on a continuing basis, optimum yield from the groundfish fisheries." (*e.g.,* Notice of Availability, 80 FR 66486, 66487, October 29, 2015; Proposed Rule, 80 FR 71650, 71651, November 16, 2015). These statements indicate that halibut PSC limit reductions are only practicable if the reductions allow for optimum yield in the groundfish fishery. National Standard 1 and National Standard 9, read together, require that necessary and practicable bycatch reduction measures must be implemented, even if that results in a downward adjustment in the optimum yield of the BSAI groundfish fishery.

Response: The preferred alternative that is implemented by this final rule balances the need to minimize halibut bycatch to the extent practicable, consistent with National Standard 9, with the requirement to achieve optimum yield in the groundfish fishery, consistent with National Standard 1. In developing the preferred alternative, NMFS and the Council have appropriately balanced obligations under National Standard 1 and National Standard 9.

Section 1.2 of the Analysis states: "The purpose of the proposed action is to minimize halibut PSC in the commercial groundfish fisheries to the extent practicable, *while preserving the potential for the optimum harvest of the groundfish TACs assigned to the trawl and non-trawl sectors.*" (emphasis added) The preferred alternative selected by the Council and implemented by this final rule preserves the potential for the BSAI groundfish fisheries to achieve optimum yield by harvesting the TACs assigned to the different BSAI groundfish fisheries. However, this final rule may result in some BSAI groundfish fisheries, in some years, harvesting less than their TACs.

The Council and NMFS did not exclude the preferred alternative implemented by this final rule because it may result in a decrease in groundfish harvests in some groundfish fisheries in some years. The Analysis before the Council and NMFS states that the halibut PSC limit reductions imposed under Amendment 111 may result in decreased harvests by the BSAI groundfish fisheries. The preamble to the proposed rule states that Amendment 111 is likely to result in groundfish harvests below the TACs for several fisheries prosecuted by the Amendment 80 sector. (80 FR 71,650, 71,663, November 16, 2015)

The Analysis estimates that Amendment 111 could result in groundfish harvest reductions in the Amendment 80 sector between 9,500 mt and 25,700 mt each year during the 10-year period considered (2014 to 2023) in the Analysis, for a total possible reduction of 95,000 mt to 257,000 mt over this 10-year period. As described in the Analysis, this could translate to a reduction in wholesale revenues for groundfish fishery participants between $6.2 million and $18.7 million for each year during this 10-year period, for a total of $62 million to $187 million throughout this 10-year period (Table ES–4 of Analysis; 80 FR 71650, 71663, November 16, 2015).

This rule provides the flexibility for participants in the groundfish fisheries to potentially harvest the TAC assigned to their fisheries. This rule minimizes bycatch to the extent practicable by recognizing that different sectors of the groundfish fisheries have available different tools to minimize halibut bycatch (see also responses to Comments 14 and 15). The fact that this rule will reduce halibut PSC limits, and likely result in reductions in groundfish harvests, supports the conclusion that Amendment 111 reflects a well-reasoned and articulated balance between National Standards 1 and 9.

Comment 9: Social and economic factors must be considered when establishing optimum yield under National Standard 1. The proposed rule does not discuss this requirement.

Response: The commenter is correct that social and economic factors are considered when establishing the optimum yield for a fishery. Optimum yield, as defined in the Magnuson-Stevens Act, is that amount of fish which "will provide the greatest overall benefit to the Nation, particularly with respect to food production and recreational opportunities, and taking into account the protection of marine ecosystems" and the amount of fish which "is prescribed as such on the basis of the maximum sustainable yield from the fishery, as reduced by any relevant economic, social, or ecological factor” (16 U.S.C. 1802(33)(A); 16 U.S.C. 1802(33)(B)). Amendment 111 and the proposed rule did not propose to change the optimum yield of the BSAI groundfish fisheries, which is specified in regulations as a range from 1.4 million to 2.0 million metric tons. (§ 679.20(a)(1)(i)(A)) Therefore NMFS did not elaborate on the factors that go into establishing optimum yield. As noted in the response to Comment 7, the requirement to establish an optimum yield does not apply to halibut.

Although Amendment 111 does not change the optimum yield established for the BSAI groundfish fisheries, fishery regulations require that the total of the TACs for the BSAI groundfish fisheries must come within the optimum yield range. (§ 679.20(a)(2)) As noted also in the response to Comment 8, the proposed rule acknowledged that Amendment 111 would likely decrease groundfish harvests below TAC for the Amendment 80 sector (80 FR 71650, 71663, November 16, 2015). The Council concluded, and NMFS agrees, that the likely economic loss from foregone harvests under this final rule is outweighed by the potential decrease in halibut bycatch and the potential increase in halibut available for the directed halibut fisheries.

Comment 10: Amendment 111 is not fair and equitable under National Standard 4. A fundamental flaw in the proposed rule and the Analysis is that the Analysis uses the status quo halibut PSC limits as the baseline for analysis. That is not fair because the directed halibut fishery has declined 63 percent in Area 4 and 67 percent in Area 4CDE from 2003 through 2013.

Response: The Analysis does evaluate a “no action” or “Status Quo” alternative. When taking action, NMFS is under an obligation to analyze a “no action” alternative in the Environmental Assessment portion of the Analysis. (Section 5.03b, NOAA Administrative Order 216–6, May 20, 1999, available at *http://www.nepa.noaa.gov/*) The Environmental Assessment would have been deficient if it did not analyze a “no action” or “Status Quo” alternative. Whether Amendment 111 is consistent with National Standard 4 is a separate question.

The Council and NMFS determined, and the Secretary concluded, that Amendment 111 is consistent with National Standard 4 (see Section 6.1 of Analysis). National Standard 4 provides that “conservation and management measures shall not discriminate between residents of different states. If it becomes necessary to allocate or assign fishing privileges among various U.S. fishermen, such allocation shall be A) fair and equitable to all such fishermen, B) reasonably calculated to promote conservation, and C) carried out in such a manner that no particular individual, corporation, or other entity acquires an excessive share of such privileges.” (16 U.S.C. 1851).

Amendment 111 does not discriminate between residents of specific states. Amendment 111 does not use residency of any fishermen, or group of fishermen, as a criterion for reduction of a PSC limit in any sector.

Amendment 111 is fair and equitable to the fishermen affected by Amendment 111. Amendment 111 reduces the PSC limits for a legitimate objective. Amendment 111 seeks to minimize halibut PSC to the extent practicable while maintaining, on a continuing basis, the potential to achieve optimum yield from the groundfish fishery. Amendment 111 achieves that objective fairly and equitably by decreasing halibut PSC limits by sector and by establishing the PSC reduction for each sector based on an evaluation of what is practicable for that sector.

The Council recommended Amendment 111 after analyzing a status quo alternative (no reductions in the halibut PSC limits for each sector) and alternatives with reductions ranging from 10 to 50 percent lower than the current halibut PSC limits in each sector. The Analysis showed that residents of various states, including Alaska and states of the Pacific Northwest, participate in the directed groundfish fisheries and the directed halibut fisheries and may be affected by this final rule. For each groundfish sector in the groundfish fisheries and for the directed halibut fisheries, the Analysis describes the participants in each fishery (Section 4.4 and 4.5 of Analysis) and the effects of each alternative, including the status quo alternative, on the groundfish fisheries and the directed halibut fisheries (Section 4.7 through 4.14 of Analysis).

In developing Amendment 111, the Council and NMFS recognized that under the status quo, the directed halibut fisheries have experienced reductions in catch limits as the halibut stock has declined (Section 4.5. of Analysis). The Analysis sets out the percentage declines cited in the comment (see text associated with Table 4–85 and Table 4–86 in Section 4.5.1 of Analysis). The Council and NMFS recognize that the reductions in halibut PSC limits in Amendment 111 will likely increase the halibut available for the directed fisheries and, in some years, may reduce groundfish harvests and therefore revenues for participants in the directed groundfish fisheries (Table ES–4 of Analysis; 80 FR 71650, 71663, November 16, 2015).

Amendment 111 is reasonably calculated to promote conservation consistent with National Standard 4. The Council and NMFS do not anticipate that Amendment 111 will have a significant effect on overall halibut mortality but do expect it to have a limited conservation benefit. The IPHC’s current measure for a juvenile halibut is a halibut that is 26 inches and under or “U26 halibut.” (Section 3.1.2.1 of Analysis) In response to this rule, the IPHC may increase the catch limits for the directed commercial halibut fishery. Even if the IPHC does that, U26 halibut still may not be retained by any fishery. This rule is expected to have a limited conservation benefit because decreasing bycatch overall will decrease bycatch of U26 halibut. Some of those U26 halibut will mature and, of those, some will reproduce.

The preamble to the proposed rule described the estimated limited conservation benefit from this action. (80 FR 71650, 71662, November 16, 2015). The Council determined, and NMFS agrees, that the reduction in U26 mortality from this action ranges from 188,000 to 210,000 pounds annually compared to the status quo. (Section 3.1.5.3 of Analysis) This conservation benefit is limited because this number of U26 halibut comprises a small proportion of the total female spawning biomass of halibut. This number of U26 halibut (188,000 to 210,000 pounds) is substantially less than 1 percent of the total female spawning biomass which, in 2015, was estimated to be 215.10 million pounds (Table 3–1 of Analysis).

Finally, consistent with National Standard 4, Amendment 111 does not result in any particular individual, corporation, or other entity acquiring an excessive share of the PSC reductions in Amendment 111. The reductions in PSC limits are spread across the individuals within each sector. The reductions in PSC limits do not change the amount of PSC that each participant in a sector has relative to other participants in the sector.

Comment 11: National Standard 5 requires that “conservation and management measures consider efficiency; except no such measure shall have economic allocation as its sole purpose.” (16 U.S.C. 1851) The guideline in Federal regulation for applying National Standard 5 states that “efficiency” refers to the wise use of all resources involved in the fishery, including ecological resources (50 CFR 600.330(e)). Reducing halibut bycatch reduces waste and constitutes wise and efficient use of the resource.

Response: NMFS agrees that reducing halibut bycatch constitutes a wise and efficient use of the resource, but accepts that some level of halibut bycatch is inevitable in the prosecution of the BSAI groundfish fisheries. Halibut bycatch is a function of the overlapping distribution of groundfish and halibut as well as regulatory requirements established by NMFS and the IPHC that require the discard of halibut harvested with trawl gear or in fisheries other than defined commercial, sport, and subsistence fisheries. Therefore, the current regulatory structure ensures that some degree of halibut bycatch must occur. The Council concluded, and NMFS agrees, that Amendment 111 reduces halibut PSC, or halibut bycatch, by the BSAI groundfish fisheries to the extent practicable consistent with National Standard 9.

Comment 12: Amendment 111 is not consistent with National Standard 8. The Analysis does not adequately evaluate the cultural and socioeconomic benefits of the halibut resource to the isolated communities of the Bering Sea, especially St. Paul and St. George, and the dozens of coastal communities throughout Alaska and the entire Pacific Coast that depend on the halibut resource for subsistence, sport, and commercial fishing and that are negatively affected by halibut bycatch.

Response: National Standard 8 provides: "Conservation and management measures shall, consistent with the conservation requirements of this Act (including the prevention of overfishing and rebuilding of overfished stocks), take into account the importance of fishery resources to fishing communities by utilizing economic and social data that meet the requirements of paragraph (2), in order to (A) provide for the sustained participation of such communities, and (B) to the extent practicable, minimize adverse economic impacts on such communities." (16 U.S.C. 1851(a)(8)). The reference to paragraph (2) is to National Standard 2: "Conservation and management measures shall be based upon the best scientific information" (16 U.S.C. 1851(a)(8)).

The Council and NMFS used the best available scientific information to assess the importance of the directed halibut fishery to various communities. For example, Appendix C to the Analysis is devoted solely to the impacts of this action on communities that are dependent on and engaged in the BSAI groundfish fisheries and communities that are dependent on and engaged in the directed halibut fisheries. Appendix C identified 15 halibut-dependent communities in the BSAI based on a variety of metrics. These communities include St. Paul and St. George (Table 1–1). Appendix C presented qualitative and quantitative information to assist the Council and NMFS in assessing the effects of this action on halibut-dependent communities and other communities by examining metrics such as the ownership of halibut catcher vessels by community (Table 2–6a); ex-vessel gross revenues from halibut catcher vessels by community (Table 2–6b); number of BSAI subsistence halibut fishermen, halibut caught, and pounds of halibut caught in Area 4 (Table 2–8); and estimated annual halibut crew and halibut crew payments by community (Table 3–10). In addition to the Analysis, the Council and NMFS had the benefit of extensive public testimony on the importance of subsistence and commercial fisheries to the residents of St. Paul and St. George and other communities engaged in the directed halibut fisheries.

Amendment 111 minimizes bycatch to the extent practicable as determined by the Council based on the best available information. Amendment 111 is expected to provide additional harvest opportunities to residents of St. George and St. Paul, based on the assumption that the IPHC will respond to the decreased bycatch resulting from Amendment 111 by increasing the commercial catch limit. Appendix C estimated the distribution of the expected increase in harvests in the directed halibut fishery in Area 4 from Amendment 111 among communities in Northwest Alaska; communities in Bristol Bay, the Aleutians and the Pribilof Islands (including St. Paul and St. George); communities in other parts of Alaska; and communities in other states (Table 4–4; Table 4–5). Appendix C also examined the potential impacts of the PSC limit reductions in Amendment 111 on BSAI communities engaged in the halibut subsistence fishery (Section 4.2.4 of Appendix C of Analysis) and the sport halibut fishery (Section 4.2.5 of Appendix C of Analysis). The Analysis also discussed the potential long-term impacts of Amendment 111 on directed halibut fishery participants and communities reliant on the halibut resource outside of the BSAI (Section 4.14.1.2 of Analysis).

Appendix C also described the adverse impacts that Amendment 111 would likely have on communities that are substantially engaged in the directed groundfish fisheries (Table 2–1a through Table 2–5f). In selecting Amendment 111, the Council weighed the potential benefits to fishing communities against the potential adverse impacts to fishing communities that could result under each halibut PSC limit reduction alternative.

Comment 13: St. Paul and St. George are much more dependent on the halibut fisheries than Seattle, Washington and Newport, Oregon are dependent on the BSAI groundfish fisheries. The interests of St. Paul and St. George are not properly weighed in the Analysis.

Response: Under National Standard 8, conservation and management measures shall take into account the importance of fishery resources to "fishing communities." The term "fishing community" in the Magnuson-Stevens Act means "a community which is substantially dependent on or substantially engaged in the harvest or processing of fishery resources to meet social and economic needs, and includes fishing vessel owners, operators, and crew and United States fish processors that are based in such communities" (16 U.S.C. 1802(17)). An analysis of conservation and management measures should examine the effect of a proposed action on communities that are substantially dependent on the fishery resource in question and on communities that are substantially engaged with the fishery resource in question (50 CFR. 600.345(c)).

In approving Amendment 111, the Council was aware that communities such as St. Paul and St. George are substantially dependent on halibut. Appendix C of the Analysis specifically identified 15 communities that are considered to be halibut-dependent (Table ES–2 in Appendix C to Analysis). The Analysis considered the best available data on the importance of the directed halibut fisheries to halibut-dependent communities such as St. Paul and St. George. The Council and NMFS considered this information, in addition to public testimony from residents of these communities.

The Council and NMFS reviewed the Analysis and considered the impacts of Amendment 111 on communities engaged in the BSAI groundfish fishery, including Seattle and Newport. The Analysis notes that Seattle and Newport are substantially engaged in the BSAI groundfish fisheries but, because of the size of those communities, the availability of other employment and other factors, Seattle and Newport were not substantially dependent on the BSAI groundfish fisheries. The Analysis noted: "While community-level dependence is not a salient issue for the Seattle MSA, potential adverse impacts of some of the Alternative 2 options and suboptions would be profound in terms of potential loss of revenues to individual operations and sectors and potential loss of income and/or employment to relatively large numbers of individuals." (ES–5 in Appendix C to Analysis). Seattle MSA stands for Seattle Metropolitan Statistical Area.

In recommending Amendment 111, the Council weighed the benefits to halibut-dependent fishing communities from different levels of PSC reductions against the adverse impacts to communities that are substantially engaged in the BSAI groundfish fisheries.

Comment 14: Amendment 111 does not decrease bycatch to the extent practicable. Larger PSC reductions are practicable and therefore must be adopted to be consistent with National Standard 9.

Response: The Council approved Amendment 111 after considering halibut PSC limit reductions that were 10 to 50 percent lower than the current halibut PSC limits in each BSAI groundfish sector. The Council and NMFS considered the practicability of each sector to meet these revised PSC limits. The preamble to the proposed rule contains a description of the specific factors considered in the section titled "Rationale and Impacts of Amendment 111 and the Proposed Rule" (80 FR 71650, 71661—71668, November 16, 2015).

For each sector, the Council and NMFS considered the relative amount of halibut PSC for that sector compared to the total amount of halibut PSC in the BSAI; whether the sector had been able to harvest groundfish TACs with lower amounts of halibut PSC than the sector's current PSC limit; what "tools" or changes in fishery operations were available to the sector to adapt to reductions in the halibut PSC limit for that sector; and the potential socioeconomic impacts of reduced halibut PSC limits for each sector. As part of the last consideration, the Council and NMFS considered the potential adverse socioeconomic impacts of halibut PSC limit reductions from reduced groundfish harvests on harvesters of BSAI groundfish and on fishing communities that participate in the groundfish fisheries, as well the potential benefits to the harvesters of halibut and to fishing communities that participate in the halibut fishery. (Proposed Rule, 80 FR 71650, 71663, November 16, 2015).

Based on these factors and the information described in the Analysis and the preamble to the proposed rule, the Council recommended and NMFS implemented the halibut PSC limits described in this final rule. A brief summary for each of the sectors follows.

For the Amendment 80 sector, Amendment 111 reduces the PSC limit by 25 percent: from 2,325 to 1,745 mt. The Amendment 80 sector is the sector that uses the largest amount of halibut PSC. The Amendment 80 sector is responsible for about 60 percent of halibut PSC use, based on average PSC usage from 2008 through 2014 (Table 1, Proposed Rule, 80 FR 71650, 71660, November 16, 2015). This final rule imposes the largest halibut PSC limit reduction on the sector which is most able to decrease bycatch through behavioral changes. The Amendment 80 sector is prosecuted by Amendment 80 cooperatives. Amendment 80 cooperatives have the power to coordinate the responses of their members to reduced PSC limits. Amendment 80 cooperatives are also more able to adopt tools to decrease bycatch as compared to a sector where individual fishery participants engage in a "race for fish" against other participants in a sector. The tools to decrease bycatch are behavior changes such as expanding the use of gear modifications known as excluders to reduce bycatch; improving communication on the fishing grounds within and between the Amendment 80 cooperatives; using test hauls to gauge halibut rates and considering the use of night-time hauls that tend to have lower halibut PSC. The tools to reduce PSC—those just mentioned and others—are described in the proposed rule (80 FR 71650, 71664, November 16, 2015) and in further detail in Section 3.1.3.6 and Appendix B of the Analysis.

The Council considered, and rejected, alternatives that would have adopted greater reductions in the PSC limit for the Amendment 80 sector. The proposed rule summarizes the Council and NMFS' reasoning for concluding that greater reductions were not practicable for the Amendment 80 sector (80 FR 71650, 71664, November 16, 2015). The Council and NMFS concluded that alternatives that would have reduced the halibut PSC limit by 30, 35, 40, 45, or 50 percent in the Amendment 80 sector would have come at significant economic cost to the Amendment 80 sector and fishing communities participating in the Amendment 80 fisheries. Based on the best available information, the Council and NMFS concluded that it was not clear that the Amendment 80 sector could make additional changes in fishery operations to accommodate higher PSC limit reductions other than foregoing substantial harvests and revenue. The Council and NMFS concluded that greater PSC reductions in the Amendment 80 sector would have reduced net benefits to the Nation "because the socioeconomic benefits from the potential increase in harvest opportunities would be less than the negative socioeconomic impacts from foregone BSAI groundfish harvests." (Proposed Rule, 80 FR 71650, 71664, November 16, 2015).

For the BSAI trawl limited access sector, Amendment 111 reduces the PSC limit by 15 percent: from 875 mt to 745 mt. This sector has used, on average from 2008 through 2014, 710 mt; in all of those years, it used less than 745 mt except in 2012, when it used 960 mt of halibut PSC (Table 1 in Proposed Rule, 80 FR 71650, 71660, November 16, 2015; Table 3–12 of Analysis).

Unlike the Amendment 80 sector, the "race for fish" still exists in large parts of the BSAI trawl limited access sector, specifically in the Pacific cod and yellowfin sole fisheries (Section 4.9 of Analysis; Proposed Rule, 80 FR 71650, 71666, November 16, 2015.) This affects what bycatch reduction is practicable for this sector. The Council recommended, and NMFS proposed, a 15 percent reduction in the halibut PSC limit for the BSAI trawl limited access sector after considering the relatively limited amount of halibut PSC in this sector; the more limited tools available to the sector to reduce its halibut PSC use; the overall socioeconomic cost to the sector, communities participating in the sector, and the Nation from larger reductions in the PSC limit for this sector; and the limited benefits that larger reductions in the PSC limit for this sector might provide to the halibut fisheries and communities participating in the halibut fisheries. The Council and NMFS also determined that the reduced halibut PSC limit in this final rule is likely to provide incentives for the BSAI trawl limited access sector to more fully develop and use tools that could improve on the relatively low PSC use that this sector achieved in 2010 and 2011. (Table 4–209 of Analysis; Proposed Rule, 80 FR 71650, 71666, November 16, 2015)

For the BSAI non-trawl limited access sector, Amendment 111 reduces the halibut PSC limit by 15 percent: from 833 mt to 710 mt. This sector has used, on average, 505 mt of halibut PSC from 2008 through 2014 (Table 1 in Proposed Rule, 80 FR 71659, 71660, November 16, 2015). The Council and NMFS did not consider greater reductions in halibut PSC limits to be practicable. Therefore, the Council did not recommend, and

NMFS does not propose, larger reductions in the PSC limit for the non-trawl sector given this sector's relatively limited use of halibut PSC; this sector's consistent pattern of halibut PSC use well below its PSC limit; and the limited benefit that larger PSC reductions would likely provide to the halibut fishery and communities participating in the halibut fishery relative to the negative impacts on participants in the non-trawl sector. (Proposed Rule, 80 FR 71650, 71667, November 16, 2015)

For the CDQ Program, Amendment 111 reduces the PSC limit by 20 percent: from 393 mt to 315 mt. The CDQ Program has used, on average, 215 mt of halibut PSC from 2008 through 2014. The Council and NMFS considered greater reductions in the PSC limit for this sector also but concluded that greater reductions were not practicable. The Analysis shows that the halibut PSC limit reductions for the CDQ Program would have to be extremely high to yield actual reductions. A 50 percent reduction in the PSC limit for the CDQ Program would reduce the PSC limit from 393 mt to 197 mt. A PSC limit of 197 mt for the CDQ Program would yield only 18 mt of halibut savings compared to the CDQ Program's average use of halibut PSC of 215 mt from 2008 through 2014 (Table 1 in Proposed Rule, 80 FR 71650, 71660, November 16, 2915). A PSC limit of 197 mt for the CDQ Program would yield only 47 mt of halibut savings relative to the CDQ Program's use of halibut PSC of 244 mt in 2014. (Table 4–209 of Analysis) Neither the Analysis nor public testimony suggests that halibut PSC use in the CDQ Program will increase relative to current use. Therefore, the Council and NMFS determined that it is impracticable to adopt a PSC limit that would substantially constrain the vessels participating in the CDQ Program, given the limited amount of PSC by the CDQ Program and the limited potential harvest opportunity for the commercial halibut fishery that a more restrictive halibut PSC limit for the CDQ Program would provide. (Proposed Rule, 80 FR 71650, 71667, November 16, 2015)

Comment 15: Amendment 111 does not minimize bycatch to the extent practicable as required under National Standard 9 because the BSAI groundfish fisheries do not use the maximum amount of their halibut PSC limits every year. Other management approaches should be tried.

Response: The commenter is correct that most sectors in the BSAI groundfish fisheries have been using less halibut PSC than their current PSC limit (Table 1 in Proposed Rule, 80 FR 71650, 71660, November 16, 2015). However, the halibut PSC limits established by this final rule are expected to limit halibut PSC use for the Amendment 80 sector relative to current use. The halibut PSC limit established for the Amendment 80 sector in this final rule is 1,745 mt. From 2008 through 2014, the Amendment 80 sector used more than 1,745 mt of halibut PSC every year. In 2015, for the first time, the Amendment 80 sector used 1,636 mt of halibut PSC, which is less than the new PSC limit of 1,745 mt. In establishing the new halibut PSC limit for the Amendment 80 sector, the Council and NMFS took into account the sector's history of PSC use and information that the Amendment 80 sector could make behavioral changes to decrease PSC levels below its PSC levels from 2008 through 2014 (Section 3.1.3.6 of Analysis; Section 14.4.2.2 of Analysis; Appendix B of Analysis; Proposed Rule, 80 FR 71650, 71664, November 16, 2015).

For the BSAI trawl limited access, BSAI non-trawl, and CDQ sectors, the Council and NMFS were aware that these sectors generally used less halibut PSC than their PSC limit (Table 1 to Proposed Rule, 80 FR 71650, 71660, November 16, 2015). The response to Comment 14 explains why the Council and NMFS concluded that greater reductions than implemented in this final rule are not practicable.

Other management approaches to manage halibut bycatch are outside of the scope of this proposed rule. NMFS lists some of the suggestions it has received for alternative halibut bycatch management measures in Comment 6 and describes some actions that are underway or under consideration in the response to Comment 6.

Comment 16: The halibut PSC limit reductions mandated in Amendment 111 will be very difficult for the Amendment 80 sector to achieve. The halibut PSC limits imposed on the Amendment 80 sector strain, and probably exceed, the limits of practicability under National Standard 9.

Response: The Council determined that the PSC limit reductions in Amendment 111 were practicable and were consistent with National Standard 9 by considering the factors summarized in the response to Comment 14 and detailed in the Analysis and the preamble to the proposed rule. NMFS notes that the use of halibut PSC in the Amendment 80 sector during 2015 supports the conclusion that the halibut PSC limit established by this final rule is practicable. In 2015, the Amendment 80 sector used 1,636 mt of halibut PSC. That amount of halibut PSC is less than the new halibut PSC limit in this rule of 1,745 mt. The Amendment 80 sector achieved this even though no regulatory provisions were in place during 2015 requiring such a substantial reduction in halibut PSC use relative to the recent average use of halibut PSC of 2,047 mt. from 2008 through 2014.

Comment 17: Technologies exist that can further decrease halibut bycatch in the Amendment 80 fleet. These include 1) the use of wide mesh nets to allow juvenile halibut to escape; 2) an underwater camera system that allows vessel operators to detect and release net-loads containing disproportionately high amounts of halibut bycatch underwater; and 3) other gear modifications to reduce halibut bycatch.

Response: The ability of the Amendment 80 fleet to develop and use new technologies to decrease halibut bycatch was one of the reasons that the Council and NMFS concluded that the PSC reductions in Amendment 111 were practicable. Amendment 111 establishes an incentive for the Amendment 80 fleet to experiment with, and use, technologies such as the ones described by the commenter.

Comment 18: Mandatory deck sorting of halibut (returning halibut to sea as quickly as possible after the harvest comes onboard) should be required so that halibut to be returned swiftly to the water. This would decrease the mortality of halibut bycatch.

Response: Mandatory deck sorting of halibut bycatch is outside of the scope of Amendment 111and is not allowed under current regulations. To conduct deck sorting, a vessel operator must have an exemption from current regulations that prevent deck sorting. In 2015, NMFS granted an exempted fishing permit for vessels in the Amendment 80 sector to test the conditions necessary to effectively conduct deck sorting and evaluate whether deck sorting decreased mortality of halibut bycatch (Appendix A–7 of the Analysis). The results from this exempted fishing permit, and other research, indicates that deck sorting can reduce the discard mortality of halibut under some conditions. In 2016, NMFS received an application for another exempted fishing permit for deck sorting, including participants in the Amendment 80 sector and the BSAI trawl limited access sector (Notice, 81 FR 4018, January 25, 2016). After reviewing the results from these exempted fishing permits and other research, the Council and NMFS may choose to begin the analytic process necessary to consider changing regulations to allow or require halibut deck sorting.

Comment 19: Hook-and-line catcher/processors have successfully decreased their halibut bycatch mortality. From 1994 to 2014, hook-and-line catcher/processors reduced their use of halibut PSC by 58 percent; reduced their halibut discard mortality rate by 47 percent; and reduced the encounter rate of halibut bycatch by 41 percent. It is possible to decrease halibut mortality through voluntary efforts rather than through regulations that implement lower halibut PSC limits.

Response: NMFS acknowledges that hook-and-line catcher/processors have taken a number of steps to reduce halibut PSC use during the period described by the commenter. Table 3–14 of the Analysis provides a description of the use of halibut PSC by hook-and-line catcher/processors from 2008 through 2014.

Comment 20: Amendment 111 does not adequately take into account the effect of halibut bycatch on the recreational (sport) halibut fishery.

Response: Under the current IPHC policy, for those IPHC management areas that occur in the BSAI (Areas 4A, 4B, and 4CDE), the IPHC deducts bycatch, sport, and subsistence halibut removals before establishing the commercial catch limit (Section 3.1.2.1 of Analysis). The IPHC does not deduct halibut used as bycatch from the amount that would otherwise be available for harvest in the Area 4 sport fishery. Therefore, unlike the case for the commercial halibut fishery, a reduction in halibut PSC limits would not directly affect the Area 4 sport fishery by making more halibut directly available for allocation to the sport fishery (Section 4.5.2 to Appendix C of Analysis). The response to Comment 21 describes how this final rule may provide a limited but long-term benefit to the sport fishery in Area 4 as well as sport fisheries in other IPHC areas.

Comment 21: Amendment 111 will not only benefit the directed commercial halibut fishery. It will also benefit sport and subsistence fisheries.

Response: The primary benefit of Amendment 111 will be to reduce the total amount of halibut bycatch removals in the BSAI (Area 4) before commercial catch limits are established, thereby increasing the amount of halibut available for commercial fishery harvests in Area 4. NMFS agrees with the commenter that Amendment 111 has the potential to provide a modest benefit to recreational and subsistence halibut fisheries as well as commercial halibut fisheries. This final rule would be expected to provide a modest long-term benefit to sport and subsistence fisheries by decreasing the bycatch of U26 halibut (the IPHC's current measure for juvenile halibut). U26 halibut are expected to grow over time and become available for harvest in sport and subsistence fisheries. (Table 3–1 in Section 3.1.1 of Analysis; 80 FR 71650, 71662, November 16, 2015). NMFS stated in the proposed rule that the specific long-term impacts of reduced U26 bycatch on potential long-term commercial, personal use, sport or subsistence harvests of halibut in specific IPHC areas "cannot be predicted with certainty given the available information." (80 FR 71650, 71662, November 16, 2015)

Comments Associated With Halibut Biology and Conservation

Comment 22: Amendment 111 does not adhere to a precautionary approach of management by protecting the halibut resource from the effects of halibut PSC use in the BSAI groundfish fisheries.

Response: This final rule follows the precautionary principle by implementing conservation measures to reduce overall halibut PSC in the groundfish fisheries even though there is limited data and information to determine the impact of halibut PSC on halibut stocks. Although the effects of halibut PSC in the groundfish fishery on the halibut fishery are uncertain, this action reduces the overall potential impacts by reducing existing halibut PSC limits in the groundfish fisheries. The halibut PSC limit reductions in the groundfish fisheries minimize bycatch to the extent practicable given the tools currently available to the sectors, the prosecution of the fishery, the uncertainty about the overall adverse effects of bycatch on the halibut stocks, and the need to ensure that the trawl and hook-and-line fisheries contribute to the achievement of optimum yield in the groundfish fisheries.

The preamble to the proposed rule and Section 3.1.1 of the Analysis presents a summary of the current condition of the Pacific halibut stock. (80 FR 71650, 71651–71652, November 16, 2015) The preamble to the proposed rule concludes that, based on the best available information, the current status of exploitable halibut biomass and female halibut spawning biomass is "that the halibut stock is stable or potentially increasing slightly in overall abundance." (80 FR 71650, 71651, November 16, 2015) The preamble to the proposed rule also notes that "even under the greatest PSC limit reduction alternatives considered, this reduction would represent less than 1 percent of the 2015 coastwide female spawning halibut biomass (see Table 3–2 in Section 3.1.1 of the Analysis)." (80 FR 71650, 71662, November 16, 2015). The halibut PSC limits established by this final rule are appropriately precautionary given the status of the halibut resource.

Comment 23: Amendment 111 does not protect juvenile halibut.

Response: By reducing halibut bycatch, Amendment 111 will decrease the amount of halibut taken by the groundfish fisheries; this reduces bycatch of juvenile halibut. The best available information shows that the halibut PSC limit reductions established in Amendment 111 will decrease U26 halibut bycatch (a size of halibut considered by the IPHC to represent juvenile halibut) by 188,000 to 210,000 pounds annually relative to recent halibut PSC use. (Proposed Rule, 80 FR 71650, 71662, November 16, 2015)

Comment 24: The Closed Area in the Bering Sea was established by the IPHC to protect juvenile halibut. The Closed Area was formerly closed to both the directed halibut fisheries and the BSAI groundfish fisheries. The reopening of the Closed Area to trawl fisheries removed a significant protection to juvenile halibut.

Response: NMFS responds in two ways. First, the commenter is correct in that the Closed Area was established by the IPHC in 1967 to protect juvenile halibut in response to severe declines in halibut abundance. Whether the Closed Area should be open to the directed halibut fishery is a matter for the IPHC to decide and is outside the scope of this rule. The IPHC assessed the impact of the Closed Area recently. An IPHC staff report prepared in 2012 concluded that "from a halibut assessment and management perspective, there was no continued purpose in maintaining the current Closed Area to the commercial halibut fishery in the eastern Bering Sea" (Section 3.1.2.4 of Analysis). Second, as described in the preamble to the proposed rule and section 3.1.1 of the Analysis, the current status of the halibut stock as measured by exploitable biomass and female spawning biomass is stable or potentially increasing slightly in abundance. (80 FR 71650, 71651–71652, November 16, 2015) The fact that the Closed Area is open to the directed groundfish fisheries does not appear to have had a deleterious effect on the halibut stock. In any event, a prohibition on fishing for groundfish in the Closed Area is outside the scope of this action.

Comment 25: The IPHC's assumption that natural mortality is the same for all age classes of halibut is not realistic and overestimates the future contribution of smaller age classes to the halibut stock.

Response: The IPHC makes assumptions about several variables in its annual assessment of the halibut stock. Section 3.1.5.1 of the Analysis describes areas of uncertainty in the IPHC's stock assessment process, including uncertainties about the natural mortality rates for halibut for various age classes. Regardless of the effect of the IPHC's assumptions about halibut natural mortality, National Standard 9 requires conservation and management measures to minimize halibut bycatch in the BSAI groundfish fisheries to the extent practicable.

Comments Associated With Fisheries Management

Comment 26: The current management of halibut PSC is not abundance-based. The current management system allows the proportion of halibut removals taken as halibut bycatch to increase as halibut abundance decreases. NMFS should set halibut PSC limits based on the abundance of halibut. An abundance-based PSC limit would protect the Bering Sea ecosystem.

Response: The commenter is correct that the current management of halibut PSC is not abundance-based. Halibut PSC limits are established in regulation as specific amounts of halibut mortality. These halibut PSC limits are not scaled to changes in halibut abundance. The change from fixed halibut PSC limits to halibut PSC limits that change with the abundance of the halibut resource is outside of the scope of this rule. The Council, in conjunction with NMFS and the IPHC, is evaluating whether it would be feasible to establish halibut PSC limits that vary with abundance (see response to comment 6).

Comment 27: The preamble to the proposed rule states that the IPHC can adopt harvest control rules to protect the halibut stock during times of low abundance and that these harvest control rules have not been triggered even during the most recent years of low exploitable halibut biomass (80 FR 71650, 71652 (November 16, 2015). This ignores the fact that the IPHC cannot curtail the PSC take of halibut bycatch in the groundfish fisheries and does not excuse inaction by the Council and NMFS.

Response: The statement cited by the commenter was in a section of the preamble to the proposed rule titled "The Status of the Halibut Stock." The conclusion in that section of the preamble was that "[t]he best available data indicate that at current levels of removals, the halibut biomass would be expected to be stable, and well above the thresholds established by the IPHC" for imposing the harvest control rules. (80 FR 71650, 71652, November 16, 2015). The Council and NMFS used this information, and other information, to understand the status of the halibut resource and the potential impact of this final rule on the halibut resource.

NMFS agrees that the IPHC does not manage the use of halibut PSC in the BSAI groundfish fisheries. The Council and NMFS have the authority to manage halibut PSC in the groundfish fisheries. NMFS agrees that the current status of the halibut resource does not preclude action by the Council or NMFS, and it has not precluded the action taken in this final rule, to reduce halibut PSC.

Comment 28: The IPHC has consistently overestimated halibut biomass and therefore has set commercial catch limits too high in the recent past. The decline in commercial catch limits from 2013 through 2015 is due in part to more accurate information about the status of halibut biomass.

Response: The commenter is correct that in 2012, IPHC staff reported that the IPHC had consistently overestimated halibut biomass and underestimated halibut harvest rates due to a retrospective bias in the IPHC's stock assessments (Section 3.1.1.1 of Analysis). The commenter is also correct that the IPHC's efforts to correct this bias is one reason that commercial catch limits declined from 2013 through 2015 compared to prior years. Although these factors have contributed to recent declines in commercial catch limits, these factors do not preclude NMFS from reviewing and undertaking actions, such as this final rule, to minimize halibut bycatch to the extent practicable consistent with National Standard 9.

Comments Associated With the Analysis (Not Discussed Under Other Comments)

Comment 29: The Analysis states that larger halibut PSC limit reductions would not significantly conserve the halibut resource by protecting more juvenile halibut. This conclusion strains reason and credibility.

Response: The conclusion of the Analysis is credible and reasonable and is based on the best available information. The IPHC's current measure for a juvenile halibut is a halibut that is 26 inches and under or "U26 halibut." (Section 3.1.2.1 of Analysis) The best available information is that approximately 36 percent of halibut PSC mortality in the BSAI is U26 halibut. (Table 4–210 in Section 4.14.1.4 of Analysis; Proposed Rule, 80 FR 71650, 71662, November 16, 2015) Ultimately, reductions in U26 bycatch could provide an opportunity for additional halibut to grow, reproduce, and eventually recruit to the halibut fishery (*i.e.,* be available for harvest). The extent to which a decrease in U26 halibut PSC may affect the coastwide female spawning biomass is not well-known based on the best available information. (Section 3.1.1.2 of the Analysis) However, the best available information suggests that reductions in U26 halibut PSC under this rule are unlikely to impact the long-term abundance of the halibut stock. Even with a 50 percent reduction in PSC limits, the largest PSC reduction considered by the Council and NMFS, the reduction in the amount of U26 halibut PSC used relative to current use would likely range from 690,000 pounds to 740,000 pounds. (Proposed Rule, 80 FR 71650, 71662, November 16, 2015) This amount would represent less than 1 percent of the 2015 coastwide female spawning biomass, which was 215.1 million pounds in 2015 (Table 3–1 of Analysis). Under the halibut PSC limit reductions established in this final rule, the reduction in U26 halibut PSC use is expected to range from 188,000 to 210,000 pounds. (Proposed Rule, 80 FR 71650, 71662, November 16, 2015) This amount represents substantially less than 1 percent of the 2015 coastwide female spawning biomass of 215.1 million pounds.

Comment 30: The Analysis focused on the economic costs of reducing halibut PSC limits on the BSAI groundfish fisheries without discussing the practicability for the groundfish fleet to make greater reductions. The Iterative Multi-year Simulation Model (IMS) in the Analysis presented two scenarios to describe potential economic impacts. Under one of those scenarios, the IMS predicted that bycatch could not be reduced without closing groundfish fisheries, an assumption that the SSC identified as unrealistic in its June 2015 Report to the Council meeting (at *http://www.npfmc.org/bsai-halibut-bycatch/*).

Response: The commenter is referring to a simulation model that was used, along with other information, to provide a quantitative estimate of the economic impacts of different levels of PSC reductions on the BSAI groundfish fisheries. Section 4.6 of the Analysis describes the simulation model.

The commenter is correct that the SSC identified that a deficiency in the model was the assumption that halibut PSC mortality could not be reduced without some decrease in groundfish harvests. This assumption is explicitly identified as Assumption 34 of the simulation model. Assumption 34 states that there are no "cost-free behavioral changes" by which vessels in the BSAI groundfish fisheries could decrease halibut PSC mortality. (Section 4.6.3 of Analysis)

However, the Analysis did not limit its discussion of potential economic impacts on the BSAI groundfish fisheries to the quantitative results of the model. The Analysis describes behavioral and operational changes that are being made, or that could be expanded or improved, in response to a decrease in PSC limits. Section 3.1.3.6 of the Analysis describes "PSC reduction tools" in the BSAI groundfish fisheries. Section 4.14.2.2 describes the "Response to PSC limit reductions." Appendix B of the Analysis describes "Mitigation of PSC Reduction Impacts."

Finally, despite this and some other limitations in the model noted by the SSC, the SSC concluded the estimates of foregone revenues provided by the analytic model "likely provides an upper bound" of impacts on the groundfish fleet "as harvesters can mitigate their foregone revenue by fishing in other fisheries, in cleaner areas, or changing gear deployment of fishing practices" (June 2015 SSC Report: *http://www.npfmc.org/bsai-halibut-bycatch/* at page 10).

The Council received the SSC Report and considered it, along with all the information in the record, when it approved Amendment 111. Neither the Council nor NMFS limited review or consideration of the potential social or economic impacts of Amendment 111 on the BSAI groundfish fisheries to this specific assumption in the IMS.

Comment 31: The Analysis does not describe the directed halibut fisheries and the BSAI groundfish fisheries equitably, as noted by the SSC in its June 2015 SSC Report: "The uneven treatment between sectors (*e.g.,* income plurality only for halibut permit holders and demographics of employment only for trawl CPs) further confounds the ability to evaluate impacts."

Response: NMFS assumes that the commenter is referring to demographic data on employment of minority employees that was used in the environmental justice discussion. This data is provided in Attachment 4 to Appendix C of the Analysis. Appendix C in the Analysis reviewed by the SSC did not use employment as a measure of community engagement for trawl catcher/processors. Section 2.2 examined data such as trawl catcher/processors by community of vessel owner; first wholesale gross revenue by community of vessel owner; an estimate of first wholesale gross revenue diversification by community of vessel owner (what percentage of the catcher/processor's revenues came from BSAI groundfish trawl fisheries) (Table 2–2a, 2–2b, 2–2c to Appendix C in the Council Draft Analysis, May 2015, available at Archive of Council Meetings, June 2015, *www.npfmc.org/council-meeting-archive/*).

In response to the SSC comment, Appendix C in the Analysis was expanded to include estimated crew employment and payments for the directed halibut fishery for the BSAI halibut-dependent communities. This new data is shown in Tables 3–3, 3–7, 3–10, and 3–13.

The Council and NMFS used the best available information consistent with National Standard 2 in the Magnuson-Stevens Act to evaluate the impacts of this action on all the communities affected by this action. The SSC found that the Analysis provided scientific support for two general statements "around which the Council can frame a policy decision," namely, that the Analysis provided an upper bound for adverse impacts on the groundfish fisheries and that the Analysis showed that the economic and cultural footprint of the directed halibut fishery is larger than that of the groundfish fishery in many small communities (June 2015 SSC Report: *http://www.npfmc.org/bsai-halibut-bycatch/* at page 10).

Comment 32: The commenter asserts that the SSC Report in June 2015 stated that the Analysis has flaws in the "upper bound" estimate on impacts on groundfish sectors provided in the IMS.

Response: The June 2015 SSC Report stated that the upper bound estimate of potential economic impacts of Amendment 111 on the BSAI groundfish fisheries was one of the general statements "around which the Council can frame a policy decision." The "upper bound" estimate is the same as the "high impact scenario" (Scenario B) used in IMS, the results of which are described in the Analysis and summarized in Table ES–4 of the Analysis. The simulation model reported the results of two scenarios: A low impact scenario (Scenario A) and a high impact scenario (Scenario B). In the low impact scenario, fishery participants are assumed to be able to coordinate harvesting activities with other participants in the sector to achieve almost optimal efficiency in avoiding halibut PSC. In the high impact scenario, fishery participants are assumed to act individually to decrease their own PSC but not cooperatively with other participants in the sector and do not achieve optimal efficiency in avoiding halibut PSC.

The Council and NMFS considered both of these scenarios. Based on the Analysis and extensive public testimony before the Council, NMFS determined that the BSAI groundfish sectors have varying abilities to optimize efficient use of halibut PSC and "it is likely that the actual economic impacts of the proposed rule will fall within the range between the low impact and high impact scenarios presented in the Analysis." (Proposed Rule, 80 FR 71650, 71661, November 16, 2015)

Comment 33: The Council's Draft Analysis states that the revisions in the IMS described in the Analysis are based on "discussions with industry." This is not the best available science as required by National Standard 2.

Response: The reference to "discussions with industry" is in note 51 in section 4.8 of the Council's Draft Analysis of May 2015, which states: "In the initial draft of the analysis, the IMS did, in fact, make assumptions about which vessels operations would be cut under the PSC limit reductions. After further discussions with industry, there was not a clear consensus among managers on how they might proceed. Much would depend on vessels' specific operating characteristics and the demands of the market." (available at Archive of Council Meetings, June 2015, *www.npfmc.org/council-meeting-archive*).

The Council's Draft Analysis in section 4.6.2.3 at pages 253–254 describes these discussions in detail. These discussions were with "industry and fishery managers," and were not limited to industry participants. These discussions were used to help define which of the four BSAI groundfish sectors should be described as catch share fisheries (and therefore more likely to be subject to economic impacts described under the low impact scenario) and which fisheries should be described as "race for fish" fisheries (and therefore more likely to be subject to economic impacts described under the high impact scenario). The final Analysis repeats the description of these discussions from the Council Draft Analysis and repeats in two places the footnote cited by the commenter (Section 4.6.2.3; Section 4.8 at note 48; Section 4.13.2.1 at note 55).

The result of the discussions was noted in the description of Assumption 42b in Section 4.6.3 of the Analysis. Assumption 42b describes the assumptions used in the model about how participants in catch share sectors (the Amendment 80 and the BSAI non-trawl sector) would respond to decreases in PSC limits. Based on these discussions, Assumption 42b was changed so that the model "[did] not make any assumptions regarding the deactivation of individual vessels" in response to reductions in PSC limits. Previously, "[i]n the initial draft of the analysis, the IMS model did in fact make assumptions about which vessel's operations would be cut under the PSC limits reductions" (Section 4.6.3 of Analysis at note 45).

Thus, the discussions with industry [1] were not just with industry but also with fishery managers, [2] resulted in a change of one assumption in the model, not a new model, [3] were an appropriate subject for gathering information from industry, namely how a company with a number of vessels would react to PSC limit reductions, and [4] resulted in a valid change in the model. This is an example of the use of best available information consistent with National Standard 2.

Comment 34: Halibut is primarily consumed domestically while groundfish with its high halibut bycatch rates is primarily exported. These values are not adequately evaluated in the Analysis.

Response: The Analysis describes the range of ex-vessel and wholesale values of halibut and groundfish fisheries. Although halibut and many groundfish species may have different markets, the impact of domestic and foreign markets is reflected in the ex-vessel and wholesale values of the fisheries described in the Analysis.

Comment 35: The Analysis overlooks the fact that the number of halibut caught, not the poundage, is the key to evaluating the population effects on the halibut stock of halibut bycatch.

Response: This action reduces the BSAI halibut PSC limits which are set as a limit on the total weight of halibut mortality that may be taken as bycatch. The Analysis appropriately assessed the impacts of the management alternatives based on the regulatory mechanism used to establish halibut PSC limits. Changing halibut PSC limits so that these limits restrict the number of halibut caught as bycatch is beyond the scope of Amendment 111. As noted in response to Comment 6, the Council, NMFS, and the IPHC are considering the potential for establishing halibut PSC limits based on the number of halibut. Any evaluation about the potential impacts of this alternative management approach would have to be considered under a separate action.

Other Issues

Comment 36: Worldwide, the rate at which fish are being taken from the oceans is unsustainable. Amendment 111 represents a scratch on the surface of what we need to do worldwide.

Response: It is beyond the scope of this final rule, and the Analysis prepared for this rule, to evaluate the worldwide management of fisheries. NMFS appreciates that the commenter believes that Amendment 111 is a step in furtherance of sustainable fisheries.

Comment 37: Establishing a separate PSC limit for CDQ groups is a good idea. The commenter criticized CDQ groups concerning their non-profit status and other aspects of their fishing operations.

Response: NMFS acknowledges the commenter's support for the part of this rule that establishes a separate BSAI halibut PSC limit for CDQ Program. Comments on other aspects of the CDQ Program are beyond the scope of this final rule.

Comment 38: As federally recognized tribal communities, protection of fishing rights in St. Paul and St. George is a shared role of both NOAA and the Department of the Interior. One commenter stated that halibut PSC limit reductions of 40 percent are necessary to protect the federally recognized fishing rights of these tribes. One tribal government passed a resolution supporting a 50 percent reduction in all halibut PSC limits in BSAI, but also requested implementation of Amendment 111.

Response: The Council recommended, and NMFS implements, Amendment 111 under the authority of the Magnuson-Stevens Act. Amendment 111 reduces halibut PSC limits in a manner that could provide additional halibut harvest opportunities for residents of St. George and St. Paul and for the tribal governments of St. George and St. Paul. The three tribal governments that submitted comments, including the tribal government that passed a resolution supporting a 50 percent reduction in BSAI halibut PSC limits, supported adoption and implementation of Amendment 111.

Comment 39: The commenter requested a description of the standard for determining conflicts of interest for the IPHC.

Response: This rule deals with conservation and management measures developed by the Council and approved and implemented by the Secretary under the Magnuson-Stevens Act. The provisions for U.S. Commissioners to participate in issues before the IPHC are beyond the scope of this rule.

Additional Action Accompanying This Rule

With this rule, NMFS also publishes revised Groundfish Harvest Specification tables with revised apportionments of BSAI halibut PSC limits. At its December 2015 Council meeting, the Council approved two sets of tables that apportion the BSAI halibut PSC limits for the 2016 and 2017 annual harvest specifications: One apportionment based on the PSC limits in effect before this final rule and one apportionment based on the PSC limits that would be in effect if this final rule were approved. (*http://www.npfmc.org/council-meeting-archive/*). The Council approved both sets of apportionments of the BSAI halibut PSC limits so that the apportionments based on the new PSC limits would go into effect when this final rule establishing the new PSC limits went into effect. Therefore, with this final rule, NMFS publishes revised Tables 14, 16, 17, and 18 for the BSAI Groundfish Harvest Specification tables. These tables supersede the prior tables of the same number that were published in the **Federal Register** on March 18, 2016 (80 FR 14773, 14787–14788). The revised Tables 14, 16, 17, and 18 are printed below.

TABLE 14—FINAL 2016 AND 2017 APPORTIONMENT OF PROHIBITED SPECIES CATCH ALLOWANCES TO NON-TRAWL GEAR, THE CDQ PROGRAM, AMENDMENT 80, AND THE BSAI TRAWL LIMITED ACCESS SECTORS

PSC species and area [1]	Non-trawl PSC remaining after CDQ PSQ [2]	Total trawl PSC	Trawl PSC remaining after CDQ PSQ [2]	CDQ PSQ reserve [2]	Amendment 80 sector [3]	BSAI trawl limited access fishery
Halibut mortality (mt) BSAI	710	2,805	n/a	315	1,745	745
Herring (mt) BSAI	n/a	2,631	n/a	n/a	n/a	n/a
Red king crab (animals) Zone 1	n/a	97,000	86,621	10,379	43,293	26,489
C. *opilio* (animals) COBLZ	n/a	4,708,314	4,204,524	503,790	2,066,524	1,351,334
C. *bairdi* crab (animals) Zone 1	n/a	830,000	741,190	88,810	312,115	348,285

TABLE 14—FINAL 2016 AND 2017 APPORTIONMENT OF PROHIBITED SPECIES CATCH ALLOWANCES TO NON-TRAWL GEAR, THE CDQ PROGRAM, AMENDMENT 80, AND THE BSAI TRAWL LIMITED ACCESS SECTORS—Continued

PSC species and area[1]	Non-trawl PSC remaining after CDQ PSQ[2]	Total trawl PSC	Trawl PSC remaining after CDQ PSQ[2]	CDQ PSQ reserve[2]	Amendment 80 sector[3]	BSAI trawl limited access fishery
C. *bairdi* crab (animals) Zone 2	n/a	2,520,000	2,250,360	269,640	532,660	1,053,394

[1] Refer to § 679.2 for definitions of zones.

[2] Section 679.21(e)(3)(i)(A)(*2*) allocates 326 mt of the trawl halibut mortality limit and § 679.21(e)(4)(i)(A) allocates 7.5 percent, or 67 mt, of the non-trawl halibut mortality limit as the PSQ reserve for use by the groundfish CDQ program. The PSQ reserve for crab species is 10.7 percent of each crab PSC limit.

[3] The Amendment 80 program reduced apportionment of the trawl PSC limits by 150 mt for halibut mortality and 20 percent for crab. These reductions are not apportioned to other gear types or sectors.

Note: Sector apportionments may not total precisely due to rounding.

TABLE 16—FINAL 2016 AND 2017 PROHIBITED SPECIES BYCATCH ALLOWANCES FOR THE BSAI TRAWL LIMITED ACCESS SECTOR

BSAI trawl limited access fisheries	Prohibited species and area[1]				
	Halibut mortality (mt) BSAI	Red king crab (animals) Zone 1	*C. opilio* (animals) COBLZ	*C. bairdi* (animals)	
				Zone 1	Zone 2
Yellowfin sole	150	23,338	1,273,886	293,234	1,005,879
Rock sole/flathead sole/other flatfish[2]	0	0	0	0	0
Greenland turbot/arrowtooth flounder/Kamchatka flounder/sablefish	0	0	0	0	0
Rockfish April 15–December 31	4	0	2,104	0	849
Pacific cod	391	2,954	54,298	50,816	42,424
Pollock/Atka mackerel/other species[3]	200	197	21,046	4,235	4,242
Total BSAI trawl limited access PSC	745	26,489	1,351,334	348,285	1,053,394

[1] Refer to § 679.2 for definitions of areas.

[2] "Other flatfish" for PSC monitoring includes all flatfish species, except for halibut (a prohibited species), flathead sole, Greenland turbot, rock sole, yellowfin sole, Kamchatka flounder, and arrowtooth flounder.

[3] "Other species" for PSC monitoring includes skates, sculpins, sharks, squids, and octopuses.

Note: Seasonal or sector apportionments may not total precisely due to rounding.

TABLE 17—FINAL 2016 AND 2017 HALIBUT PROHIBITED SPECIES BYCATCH ALLOWANCES FOR NON-TRAWL FISHERIES

Halibut mortality (mt) BSAI				
Non-trawl fisheries	Seasons	Catcher/processor	Catcher vessel	All non-trawl
Pacific cod	Total Pacific cod	648	13	n/a.
	January 1–June 10	388	9	n/a.
	June 10–August 15	162	2	n/a.
	August 15–December 31	98	2	n/a.
Non-Pacific cod non-trawl-Total	May 1–December 31	n/a	n/a	49.
Groundfish pot and jig	n/a	n/a	n/a	Exempt.
Sablefish hook-and-line	n/a	n/a	n/a	Exempt.
Total for all non-trawl PSC	n/a	n/a	n/a	710

Note: Seasonal or sector apportionments may not total precisely due to rounding.

TABLE 18—FINAL 2016 PROHIBITED SPECIES BYCATCH ALLOWANCE FOR THE BSAI AMENDMENT 80 COOPERATIVES

Cooperative	Prohibited species and zones[1]				
	Halibut mortality (mt) BSAI	Red king crab (animals) Zone 1	*C. opilio* (animals) COBLZ	*C. bairdi* (animals)	
				Zone 1	Zone 2
Alaska Groundfish Cooperative	474	12,459	650,551	82,136	137,369
Alaska Seafood Cooperative	1,271	30,834	1,415,973	229,979	395,291

[1] Refer to § 679.2 for definitions of zones.

Note: Sector apportionments may not total precisely due to rounding.

Classification

The NMFS Assistant Administrator has determined that Amendment 111 to the FMP and this rule are necessary for the conservation and management of the groundfish fishery and that it is consistent with the Magnuson-Stevens Act and other applicable law.

This rule has been determined to be not significant for the purposes of Executive Order (E.O.) 12866.

Small Entity Compliance Guide

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule or group of related rules for which an agency is required to prepare a Final Regulatory Flexibility Analysis, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as "small entity compliance guides." The preambles to the proposed rule and this final rule serve as the small entity compliance guide. This action does not require any additional compliance from small entities that is not described in the preambles. Copies of the proposed rule and this final rule are available from the NMFS Web site at *http://alaskafisheries.noaa.gov.*

Final Regulatory Flexibility Analysis

This final regulatory flexibility analysis (FRFA) incorporates the Initial Regulatory Flexibility Analysis (IRFA), a summary of the significant issues raised by the public comments, NMFS' responses to those comments, and a summary of the analyses completed to support the action. NMFS published the proposed rule on November 16, 2015 (80 FR 71650), with comments invited through December 16, 2015. An IRFA was prepared and summarized in the Classification section of the preamble to the proposed rule. The FRFA describes the impacts on small entities, which are defined in the IRFA for this action and not repeated here. Analytical requirements for the FRFA are described in Regulatory Flexibility Act, section 304(a)(1) through (5), and summarized below.

The FRFA must contain:

1. A succinct statement of the need for, and objectives of, the rule;
2. A summary of the significant issues raised by the public comments in response to the IRFA, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
3. A description and an estimate of the number of small entities to which the rule will apply, or an explanation of why no such estimate is available;
4. A description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and
5. A description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

The "universe" of entities to be considered in a FRFA generally includes only those small entities that can reasonably be expected to be directly regulated by the action. If the effects of the rule fall primarily on a distinct segment of the industry, or portion thereof (*e.g.*, user group, gear type, geographic area), that segment would be considered the universe for purposes of this analysis.

In preparing a FRFA, an agency may provide either a quantifiable or numerical description of the effects of a rule (and alternatives to the rule), or more general descriptive statements, if quantification is not practicable or reliable.

Need for and Objectives of This Final Rule

The objective of this final rule is to decrease BSAI halibut PSC to the extent practicable by the BSAI groundfish fisheries while achieving, on a continuing basis, optimum yield from the BSAI groundfish fisheries. This rule achieves that objective by reducing the BSAI halibut PSC limits in four sectors of the BSAI groundfish fisheries and adopting the following new BSAI halibut PSC limits: 1,745 mt for the Amendment 80 sector; 745 mt for the BSAI trawl limited access sector; 710 mt for the BSAI non-trawl sector; and 315 mt for the CDQ Program. These new limits result in an overall BSAI halibut PSC limit of 3,515 mt. By reducing halibut PSC, this final rule may increase harvest opportunities for the directed halibut fisheries if the IPHC responds to this final rule by increasing catch limits for the directed halibut fisheries.

Summary of Significant Issues Raised During Public Comment

No comments were received that raised significant issues in response to the IRFA specifically; therefore, no changes were made to the rule as a result of comments on the IRFA. However, several comments were received on the economic impacts of Amendment 111 on different sectors of the groundfish and halibut fisheries and on fishing communities. For a summary of the comments received and the agency's responses, refer to the section above titled "Response to Comments," particularly the sections titled "Comments Associated with Specific National Standards" and "Comments Associated with the Analysis."

Number and Description of Directly Regulated Small Entities

This action directly regulates those entities that participate in harvesting groundfish from the Federal or parallel groundfish fisheries of the BSAI subject to a halibut PSC limit. The Regulatory Flexibility Act (RFA) recognizes and defines three kinds of small entities that could be regulated by this action: (1) small businesses, (2) small non-profit organizations, and (3) small government jurisdictions. This action directly regulates small businesses that participate in the harvesting of groundfish, and small non-profit organizations.

In this FRFA, NMFS estimates the number of directly regulated small entities based on size criteria established for industry sectors defined by the Small Business Administration (SBA). According to the SBA criteria, the groundfish fishery is defined as a finfish harvesting sector. An entity primarily involved in finfish harvesting is a small entity if it is independently owned and operated and not dominant in its field of operation (including its affiliates), and if it has combined annual gross receipts not in excess of $20.5 million for all its affiliated operations worldwide. Based on the best available and most recent data from 2014, a maximum of up to 178 vessels could be directly regulated by this action. This FRFA assumes that each vessel is a unique entity. Because of that, this FRFA likely overestimates the total number of directly regulated entities because some vessels are likely affiliated through common ownership. However, these potential affiliations are not known with the best available data and cannot be predicted.

Only 19 of these directly regulated entities are estimated to be small entities based on the best available data on the gross receipts from these entities and their known affiliates. Seventeen of these small entities are hook-and-line catcher vessels that participate in the non-trawl sector, and two are trawl catcher vessels that participate in the BSAI trawl limited access sector, specifically the Pacific cod target fishery.

This final rule directly regulates all six of the CDQ groups: the Aleutian Pribilof Island Community Development Association, the Bristol Bay Economic Development Corporation, the Central Bering Sea Fishermen's Association, the Coastal Villages Region Fund, the Norton Sound Economic Development Corporation, and the Yukon Delta Fisheries Development Association. Each of the six CDQ groups receives an exclusive allocation of halibut PSC that will be reduced (*i.e.*, regulated) under this action. The six CDQ groups are non-profit organizations and none is dominant in its field; consequently each is defined as a small entity under the RFA.

Recordkeeping and Reporting Requirements

This action does not modify recordkeeping or reporting requirements.

Description of Significant Alternatives Considered

The Council considered an extensive series of alternatives, options, and suboptions to reduce halibut PSC limits in the BSAI, including the "no action" alternative. The RIR presents the complete set of alternatives (see **ADDRESSES**). Alternative 1 is the status quo/no action alternative, which would retain the current BSAI halibut PSC limits in the FMP and in regulations. Alternative 2 would have amended the FMP and regulations to reduce BSAI halibut PSC limits for six groundfish sectors. Alternative 2 includes six options. Each of the options under Alternative 2 contained seven suboptions analyzing halibut PSC limit reductions ranging from 10 percent to 50 percent for each sector. Option 1 would have reduced halibut PSC limits for the Amendment 80 sector. The reductions ranged from 232 mt to 1,162 mt. Option 2 would have reduced halibut PSC limits for the BSAI trawl limited access sector. The reductions ranged from 87 mt to 437 mt. Option 3 would have reduced halibut PSC limits for the Pacific cod hook-and-line catcher/processor sector. The reductions ranged from 76 mt to 380 mt. Option 4 would have reduced halibut PSC limits for hook-and-line vessels participating in target fisheries other than Pacific cod or sablefish. The reductions ranged from 6 mt to 29 mt. Option 5 would have reduced halibut PSC limits for the Pacific cod hook-and-line catcher vessel sector. The reductions ranged from 1 mt to 7 mt. Option 6 would have reduced halibut PSC limits for the CDQ Program. The reductions ranged from 39 mt to 196 mt. The variety of options and suboptions under Alternative 2 provided dozens of different combinations of halibut PSC limit reductions and allowed the Council and NMFS to consider a broad range of potential alternative actions.

After carefully considering these alternatives, the Council concluded that the preferred alternative represented the proper balance between achieving optimum yield by the groundfish fisheries and reducing bycatch by the groundfish fisheries to the extent practicable, taking into account the importance of the groundfish fisheries and the halibut fisheries to fishing communities. The other alternatives would have decreased bycatch by the groundfish fisheries either too much (going beyond what was practicable) or too little (falling short of what was practicable).

Section 2.5 of the Analysis describes other significant alternatives to the rule that the Council considered but did not advance for further analysis: (1) Apportioning the halibut PSC limit for the BSAI trawl limited access sector between American Fisheries Act (AFA) trawl catcher vessels and non-AFA trawl catcher vessels based on the halibut PSC by these vessel categories from 2009 through 2013; (2) implementing permanent measures in the Amendment 80 sector for deck sorting of halibut; and (3) establishing a seasonal apportionment of the halibut PSC limit for the BSAI trawl limited access sector. Each of these alternatives would have changed the current management structure for regulating halibut PSC limits in BSAI. The Council's preferred alternative is a straightforward reduction in halibut PSC limits by sector. The Council's preferred alternative leaves the current management structure intact and most expeditiously achieves the Council's objective of reducing halibut PSC limit to the extent practicable in accord with National Standard 9 and other national standards. The alternatives that were not advanced for further analysis would have taken substantially longer to develop and implement than the preferred alternative.

Based on the best available scientific data and information, none of the alternatives except the preferred alternative appear to have the potential to accomplish the stated objectives of the Magnuson-Stevens Act and other applicable statutes (as reflected in this action), while minimizing any significant adverse economic impact on small entities beyond those achieved under this action. This action will minimize bycatch to the extent practicable with existing management tools. Thus, this action will minimize the impacts on small entities in the BSAI groundfish fisheries and promote more efficient use of the available halibut PSC limits.

Tribal Consultation

Executive Order (E.O.) 13175 of November 6, 2000 (25 U.S.C. 450 note), the Executive Memorandum of April 29, 1994 (25 U.S.C. 450 note), the American Indian and Alaska Native Policy of the U.S. Department of Commerce (March 30, 1995), and the Department of Commerce Tribal Consultation and Coordination policy (78 FR 33331, June 4, 2013) outline the responsibilities of NMFS for Federal policies that have tribal implications. Section 161 of Public Law 108–199 (188 Stat. 452), as amended by section 518 of Public Law 109–447 (118 Stat. 3267), extends the consultation requirements of E.O. 13175 to Alaska Native corporations. Under the E.O. and agency policies, NMFS must ensure meaningful and timely input by tribal officials and representatives of Alaska Native corporations in the development of regulatory policies that have tribal implications.

Section 5(b)(2)(B) of E.O. 13175 requires NMFS to prepare a "tribal summary impact statement" for any regulation that has tribal implications, that imposes substantial direct compliance costs on Indian tribal governments, and is not required by statute. The tribal summary impact statement must contain (1) a description of the extent of the agency's prior consultation with tribal officials, (2) a summary of the nature of their concerns, (3) the agency's position supporting the need to issue the regulation, and (4) a statement of the extent to which the concerns of tribal officials have been met.

NMFS provided a copy of the Notice of Availability (80 FR 66486, October 29, 2015) and the proposed rule (80 FR 71650, November 16, 2015) to all federally recognized tribal governments and Alaska Native corporations to notify them of the opportunity to comment or request a consultation on this action. NMFS received no requests for consultation.

NMFS received comment on this action from three federally recognized tribes in Alaska and one Alaska Native corporation. All four entities supported adoption of Amendment 111. Three of the four entities favored larger PSC reductions than contained in Amendment 111. The preference for these commenters and other commenters for larger PSC reductions is addressed in the response to Comment 2. Even though three of these commenters favored larger PSC reductions, if the Secretary disapproved this action, there would be no reductions in the PSC limit for 2016 and no reductions in the PSC limit unless, and until, the Council and NMFS proposed a new rule adopting different PSC reductions. This would be against the interests of these four commenters, as they described those interests, in their comments because they supported adoption of the PSC reductions in Amendment 111.

List of Subjects in 50 CFR Part 679

Alaska, Fisheries, Reporting and recordkeeping requirements.

Dated: April 20, 2016.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 679 is amended as follows:

PART 679—FISHERIES OF THE EXCLUSIVE ECONOMIC ZONE OFF ALASKA

■ 1. The authority citation for 50 CFR part 679 continues to read as follows:

Authority: 16 U.S.C. 773 *et seq.;* 1801 *et seq.;* 3631 *et seq.;* Pub. L. 108–447; Pub. L. 111–281.

■ 2. In § 679.2, revise the definitions for paragraph (5) of "Directed fishing", "Herring Savings Area", "PSQ reserve", and "Sablefish (black cod)" to read as follows:

§ 679.2 Definitions.

* * * * *

Directed fishing means:

* * * * *

(5) *With respect to the harvest of flatfish in the Bering Sea subarea,* for purposes of nonpelagic trawl restrictions under § 679.22(a) and modified nonpelagic trawl gear requirements under §§ 679.7(c)(5) and 679.24(f), fishing with nonpelagic trawl gear during any fishing trip that results in a retained aggregate amount of yellowfin sole, rock sole, Greenland turbot, arrowtooth flounder, flathead sole, Alaska plaice, and other flatfish that is greater than the retained amount of any other fishery category defined under § 679.21(b)(1)(ii) or of sablefish.

* * * * *

Herring Savings Area means any of three areas in the BSAI presented in Figure 4 to this part (see also § 679.21(b)(4) for additional closure information).

* * * * *

PSQ reserve means the amount of a prohibited species catch limit established under § 679.21 that has been allocated to the CDQ Program under § 679.21.

* * * * *

Sablefish (black cod) means *Anoplopoma fimbria.* (See also *IFQ sablefish; sablefish as a prohibited species* at § 679.21(a)(5); and *sablefish as a prohibited species* at § 679.24(c)(2)(ii)).

* * * * *

■ 3. In § 679.7, revise paragraphs (a)(12), (k)(1)(v), and (k)(4)(iii) to read as follows:

§ 679.7 Prohibitions.

* * * * *

(a) * * *

(12) *Prohibited species donation program.* Retain or possess prohibited species, defined at § 679.21(a)(1), except as permitted to do so under the PSD program as provided by § 679.26, or as authorized by other applicable law.

* * * * *

(k) * * *

(1) * * *

(v) *Directed fishing after a sideboard closure.* Use a listed AFA catcher/processor or a catcher/processor designated on a listed AFA catcher/processor permit to engage in directed fishing for a groundfish species or species group in the BSAI after the Regional Administrator has issued an AFA catcher/processor sideboard directed fishing closure for that groundfish species or species group under §§ 679.20(d)(1)(iv), 679.21(b)(4)(iii), or 679.21(e)(3)(v).

* * * * *

(4) * * *

(iii) *Groundfish sideboard closures.* Use an AFA catcher vessel to engage in directed fishing for a groundfish species or species group in the BSAI or GOA after the Regional Administrator has issued an AFA catcher vessel sideboard directed fishing closure for that groundfish species or species group under §§ 679.20(d)(1)(iv), 679.21(b)(4)(iii), or 679.21(e)(3)(iv), if the vessel's AFA permit does not contain a sideboard exemption for that groundfish species or species group.

* * * * *

■ 4. In § 679.21,

■ a. Redesignate paragraph (b) as paragraph (a);

■ b. Revise newly redesignated paragraph (a)(4);

■ c. Add a new paragraph (b);

■ d. Revise paragraph (e) heading;

■ e. Remove and reserve paragraphs (e)(1)(iv), (e)(2), and (e)(3)(i)(A)(*2*);

■ f. Revise paragraph (e)(3)(ii) heading, paragraphs (e)(3)(ii)(A) and (C), (e)(3)(iv) introductory text, paragraph (e)(3)(iv)(B)(*2*) heading, (e)(3)(v), and (e)(3)(vi)(A) and (B);

■ g. Remove and reserve paragraph (e)(4);

■ h. Remove paragraph (e)(5)(iv);

■ i. Revise paragraphs (e)(6)(i) and (ii), and (e)(7)(i);

■ j. Remove and reserve paragraph (e)(7)(v); and

■ k. Remove paragraph (e)(8).

The revisions and additions read as follows:

§ 679.21 Prohibited species bycatch management.

(a) * * *

(4) *Prohibited species taken seaward of the EEZ off Alaska.* No vessel fishing for groundfish in the GOA or BSAI may have on board any species listed in this paragraph (a) that was taken in waters seaward of these management areas, regardless of whether retention of such species was authorized by other applicable laws.

* * * * *

(b) *BSAI halibut PSC limits*—(1) *Establishment of BSAI halibut PSC limits.* Subject to the provisions in paragraphs (b)(1)(i) through (iv) of this section, the following four BSAI halibut PSC limits are established, which total 3,515 mt: Amendment 80 sector—1,745 mt; BSAI trawl limited access sector—745 mt; BSAI non-trawl sector—710 mt; and CDQ Program—315 mt (established as a PSQ reserve).

(i) *Amendment 80 sector.* The PSC limit of halibut caught while conducting any fishery in the Amendment 80 sector is an amount of halibut equivalent to 1,745 mt of halibut mortality. Halibut PSC limits within the Amendment 80 sector will be established for Amendment 80 cooperatives and the Amendment 80 limited access fishery according to the procedure and formulae in § 679.91(d) and (f). If halibut PSC is assigned to the Amendment 80 limited access fishery, it will be apportioned into PSC allowances for trawl fishery categories according to the procedure in paragraphs (b)(1)(ii)(A)(*2*) and (*3*) of this section.

(ii) *BSAI trawl limited access sector*—(A) *General.* (*1*) The PSC limit of halibut caught while conducting any fishery in the BSAI trawl limited access sector is an amount of halibut equivalent to 745 mt of halibut mortality.

(*2*) NMFS, after consultation with the Council, will apportion the PSC limit set forth under paragraph (b)(1)(ii)(A)(*1*) of this section into PSC allowances for the trawl fishery categories defined in paragraphs (b)(1)(ii)(B)(*1*) through (*6*) of this section.

(*3*) Apportionment of the trawl halibut PSC limit set forth under paragraph (b)(1)(ii)(A)(*1*) of this section among the trawl fishery categories will be based on each category's proportional share of the anticipated halibut PSC during a fishing year and the need to optimize the amount of total groundfish harvested under the halibut PSC limit for this sector.

(*4*) The sum of all PSC allowances for this sector will equal the PSC limit set forth under paragraph (b)(1)(ii)(A)(*1*) of this section.

(B) *Trawl fishery categories.* For purposes of apportioning the trawl PSC limit set forth under paragraph (b)(1)(ii)(A)(*1*) of this section among trawl fisheries, the following fishery categories are specified and defined in terms of round-weight equivalents of those groundfish species or species groups for which a TAC has been specified under § 679.20.

(*1*) *Midwater pollock fishery.* Fishing with trawl gear during any weekly reporting period that results in a catch of pollock that is 95 percent or more of the total amount of groundfish caught during the week.

(*2*) *Flatfish fishery.* Fishing with trawl gear during any weekly reporting period that results in a retained aggregate amount of rock sole, "other flatfish," and yellowfin sole that is greater than the retained amount of any other fishery category defined under this paragraph (b)(1)(ii)(B).

(*i*) *Yellowfin sole fishery.* Fishing with trawl gear during any weekly reporting period that is defined as a flatfish fishery under this paragraph (b)(1)(ii)(B)(*2*) and results in a retained amount of yellowfin sole that is 70 percent or more of the retained aggregate amount of rock sole, "other flatfish," and yellowfin sole.

(*ii*) *Rock sole/flathead sole/Alaska plaice/"other flatfish" fishery.* Fishing with trawl gear during any weekly reporting period that is defined as a flatfish fishery under this paragraph (b)(1)(ii)(B)(*2*) and is not a yellowfin sole fishery as defined under paragraph (b)(1)(ii)(B)(*2*)(*i*) of this section.

(*3*) *Greenland turbot/arrowtooth flounder/Kamchatka flounder/sablefish fishery.* Fishing with trawl gear during any weekly reporting period that results in a retained aggregate amount of Greenland turbot, arrowtooth flounder, Kamchatka flounder, and sablefish that is greater than the retained amount of any other fishery category defined under this paragraph (b)(1)(ii)(B).

(*4*) *Rockfish fishery.* Fishing with trawl gear during any weekly reporting period that results in a retained aggregate amount of rockfish species that is greater than the retained amount of any other fishery category defined under this paragraph (b)(1)(ii)(B).

(*5*) *Pacific cod fishery.* Fishing with trawl gear during any weekly reporting period that results in a retained aggregate amount of Pacific cod that is greater than the retained amount of any other groundfish fishery category defined under this paragraph (b)(1)(ii)(B).

(*6*) *Pollock/Atka mackerel/"other species."* Fishing with trawl gear during any weekly reporting period that results in a retained aggregate amount of pollock other than pollock harvested in the midwater pollock fishery defined under paragraph (b)(1)(ii)(B)(*1*) of this section, Atka mackerel, and "other species" that is greater than the retained amount of any other fishery category defined under this paragraph (b)(1)(ii)(B).

(C) *Halibut PSC in midwater pollock fishery.* Any amount of halibut that is incidentally taken in the midwater pollock fishery, as defined in paragraph (b)(1)(ii)(B)(*1*) of this section, will be counted against the halibut PSC allowance specified for the pollock/Atka mackerel/"other species" category, as defined in paragraph (b)(1)(ii)(B)(*6*) of this section.

(iii) *BSAI Non-trawl Sector*—(A) *General.* (*1*) The PSC limit of halibut caught while conducting any fishery in the BSAI non-trawl sector is an amount of halibut equivalent to 710 mt of halibut mortality.

(*2*) NMFS, after consultation with the Council, will apportion the PSC limit set forth under paragraph (b)(1)(iii)(A)(*1*) into PSC allowances for the non-trawl fishery categories defined under paragraph (b)(1)(iii)(B) of this section.

(*3*) Apportionment of the non-trawl halibut PSC limit of 710 mt among the non-trawl fishery categories will be based on each category's proportional share of the anticipated halibut PSC during a fishing year and the need to optimize the amount of total groundfish harvested under the halibut PSC limit for this sector.

(*4*) The sum of all PSC allowances for this sector will equal the PSC limit set forth under paragraph (b)(1)(iii)(A)(*1*) of this section.

(B) *Non-trawl fishery categories.* For purposes of apportioning the non-trawl halibut PSC limit among fisheries, the following fishery categories are specified and defined in terms of round-weight equivalents of those BSAI groundfish species for which a TAC has been specified under § 679.20.

(*1*) *Pacific cod hook-and-line catcher vessel fishery.* Catcher vessels fishing with hook-and-line gear during any weekly reporting period that results in a retained catch of Pacific cod that is greater than the retained amount of any other groundfish species.

(*2*) *Pacific cod hook-and-line catcher/processor fishery.* Catcher/processors fishing with hook-and-line gear during any weekly reporting period that results in a retained catch of Pacific cod that is greater than the retained amount of any other groundfish species.

(*3*) *Sablefish hook-and-line fishery.* Fishing with hook-and-line gear during any weekly reporting period that results in a retained catch of sablefish that is greater than the retained amount of any other groundfish species.

(*4*) *Groundfish jig gear fishery.* Fishing with jig gear during any weekly reporting period that results in a retained catch of groundfish.

(*5*) *Groundfish pot gear fishery.* Fishing with pot gear under restrictions set forth in § 679.24(b) during any weekly reporting period that results in a retained catch of groundfish.

(*6*) *Other non-trawl fisheries.* Fishing for groundfish with non-trawl gear during any weekly reporting period that results in a retained catch of groundfish and does not qualify as a Pacific cod hook-and-line catcher vessel fishery, a Pacific cod hook-and-line catcher/processor fishery, a sablefish hook-and-line fishery, a jig gear fishery, or a groundfish pot gear fishery as defined under paragraphs (b)(1)(iii)(B)(*1*) through (*5*) of this section.

(iv) *CDQ Program.* The PSC limit of halibut caught while conducting any fishery in the CDQ Program is an amount of halibut equivalent to 315 mt of halibut mortality. The PSC limit to the CDQ Program will be treated as a Prohibited Species Quota (PSQ) reserve to the CDQ Program for all purposes under 50 CFR part 679 including §§ 679.31 and 679.7(d)(3). The PSQ limit is not apportioned by gear, fishery, or season.

(2) *Seasonal apportionments of BSAI halibut PSC allowances*—(i) *General.* NMFS, after consultation with the Council, may apportion a halibut PSC allowance on a seasonal basis.

(ii) *Factors to be considered.* NMFS will base any seasonal apportionment of a PSC allowance on the following types of information:

(A) Seasonal distribution of prohibited species;

(B) Seasonal distribution of target groundfish species relative to prohibited species distribution;

(C) Expected PSC needs on a seasonal basis relevant to change in prohibited species biomass and expected catches of target groundfish species;

(D) Expected variations in PSC rates throughout the fishing year;

(E) Expected changes in directed groundfish fishing seasons;

(F) Expected start of fishing effort; or

(G) Economic effects of establishing seasonal prohibited species apportionments on segments of the target groundfish industry.

(iii) *Seasonal trawl fishery PSC allowances*—(A) *Unused seasonal apportionments.* Unused seasonal apportionments of trawl fishery PSC allowances made under paragraph (b)(2) of this section will be added to its respective fishery PSC allowance for the next season during a current fishing year.

(B) *Seasonal apportionment exceeded.* If a seasonal apportionment of a trawl fishery PSC allowance made under paragraph (b)(2) of this section is exceeded, the amount by which the seasonal apportionment is exceeded will be deducted from its respective apportionment for the next season during a current fishing year.

(iv) *Seasonal non-trawl fishery PSC allowances*—(A) *Unused seasonal apportionments.* Any unused portion of a seasonal non-trawl fishery PSC allowance made under paragraph (b)(2) of this section will be reapportioned to the fishery's remaining seasonal PSC allowances during a current fishing year in a manner determined by NMFS, after consultation with the Council, based on the types of information listed under paragraph (b)(2)(ii) of this section.

(B) *Seasonal apportionment exceeded.* If a seasonal apportionment of a non-trawl fishery PSC allowance made under paragraph (b)(2) of this section is exceeded, the amount by which the seasonal apportionment is exceeded will be deducted from the fishery's remaining seasonal PSC allowances during a current fishing year in a manner determined by NMFS, after consultation with the Council, based on the types of information listed under paragraph (b)(2)(ii) of this section.

(3) *Notification of allowances*—(i) *General.* NMFS will publish in the **Federal Register,** for up to two fishing years, the proposed and final BSAI halibut PSC allowances, the seasonal apportionments thereof, and the manner in which seasonal apportionments of non-trawl fishery PSC allowances will be managed.

(ii) *Public comment.* Public comment will be accepted by NMFS on the proposed PSC allowances seasonal apportionments thereof, and the manner in which seasonal apportionments of non-trawl fishery PSC allowances will be managed, for a period specified in the notice of proposed specifications published in the **Federal Register.**

(4) *Management of BSAI halibut PSC allowances*—(i) *Trawl sector—Amendment 80 limited access fishery and BSAI trawl limited access sector: closures*—(A) *Exception.* When a PSC allowance, or seasonal apportionment thereof, specified for the pollock/Atka mackerel/"other species" fishery category, as defined in paragraph (b)(1)(ii)(B)(*6*) of this section is reached, only directed fishing for pollock is closed to trawl vessels using nonpelagic trawl gear.

(B) *Closures.* Except as provided in paragraph (b)(4)(i)(A) of this section, if, during the fishing year, the Regional Administrator determines that U.S. fishing vessels participating in any of the trawl fishery categories listed in paragraphs (b)(1)(ii)(B)(*2*) through (*6*) of this section will catch the halibut PSC allowance, or seasonal apportionment thereof, specified for that fishery category under paragraph (b)(1)(i) or (b)(1)(ii) of this section, NMFS will publish in the **Federal Register** the closure of the entire BSAI to directed fishing for each species and/or species group in that fishery category for the remainder of the year or for the remainder of the season.

(ii) *BSAI non-trawl sector: closures.* If, during the fishing year, the Regional Administrator determines that U.S. fishing vessels participating in any of the non-trawl fishery categories listed under paragraph (b)(1)(iii) of this section will catch the halibut PSC allowance, or seasonal apportionment thereof, specified for that fishery category under paragraph (b)(1)(iii) of this section, NMFS will publish in the **Federal Register** the closure of the entire BSAI to directed fishing with the relevant gear type for each species and/or species group in that fishery category.

(iii) *AFA PSC sideboard limits.* Halibut PSC limits for the AFA catcher/processor sector and the AFA trawl catcher vessel sector will be established pursuant to § 679.64(a) and (b) and managed through directed fishing closures for the AFA catcher/processor sector and the AFA trawl catcher vessel sector in the groundfish fisheries for which the PSC limit applies.

* * * * *

(e) *BSAI PSC limits for crab, salmon, herring*—

* * * * *

(3) * * *

(ii) *Red king crab, C. bairdi, and C. opilio*—(A) *General.* For vessels engaged in directed fishing for groundfish in the BSAI, other than vessels fishing under a CQ permit assigned to an Amendment 80 cooperative, the PSC limits for red king crab, *C. bairdi,* and *C. opilio* will be apportioned to the trawl fishery categories defined in paragraphs (e)(3)(iv)(B) through (F) of this section.

* * * * *

(C) *Incidental catch in midwater pollock fishery.* Any amount of red king crab, *C. bairdi,* or *C. opilio* that is incidentally taken in the midwater pollock fishery as defined in paragraph (e)(3)(iv)(A) of this section will be counted against the bycatch allowances specified for the pollock/Atka mackerel/"other species" category defined in paragraph (e)(3)(iv)(F) of this section.

* * * * *

(iv) *Trawl fishery categories.* For purposes of apportioning trawl PSC limits for crab and herring among fisheries, other than crab PSC CQ assigned to an Amendment 80 cooperative, the following fishery categories are specified and defined in terms of round-weight equivalents of those groundfish species or species groups for which a TAC has been specified under § 679.20.

* * * * *

(B) * * *

(*2*) *Rock sole/flathead sole/Alaska plaice/"other flatfish" fishery.* * * *

* * * * *

(v) *AFA prohibited species catch limitations.* Crab PSC limits for the AFA catcher/processor sector and the AFA trawl catcher vessel sector will be established according to the procedures and formulas set out in § 679.64(a) and (b) and managed through directed fishing closures for the AFA catcher/processor sector and the AFA trawl catcher vessel sector in the groundfish fisheries for which the PSC limit applies.

(vi) * * *

(A) Crab PSC limits for the Amendment 80 sector in the BSAI will be established according to the procedure and formulae set out in § 679.91(d) through (f); and

(B) Crab PSC assigned to the Amendment 80 limited access fishery will be managed through directed fishing closures for Amendment 80 vessels to which the crab bycatch limits apply.

* * * * *

(6) * * *

(i) *General.* NMFS will publish in the **Federal Register**, for up to two fishing years, the annual red king crab PSC limit, and, if applicable, the amount of this PSC limit specified for the RKCSS, the annual *C. bairdi* PSC limit, the annual *C. opilio* PSC limit, the proposed and final PSQ reserve amounts, the proposed and final bycatch allowances, and the seasonal apportionments thereof, as required by paragraph (e) of this section.

(ii) *Public comment.* Public comment will be accepted by NMFS on the proposed annual red king crab PSC limit and, if applicable, the amount of this PSC limit specified for the RKCSS, the annual *C. bairdi* PSC limit, the annual *C. opilio* PSC limit, the proposed and final bycatch allowances, seasonal apportionments thereof, and the manner in which seasonal apportionments of non-trawl fishery bycatch allowances will be managed, for a period specified in the notice of proposed specifications published in the **Federal Register.**

(7) * * *

(i) *Exception.* When a bycatch allowance, or seasonal apportionment thereof, specified for the pollock/Atka mackerel/"other species" fishery category is reached, only directed fishing for pollock is closed to trawl vessels using nonpelagic trawl gear.

* * * * *

■ 5. In § 679.31, revise paragraph (a)(4) to read as follows:

§ 679.31 CDQ and PSQ reserves, allocations, and transfers.

(a) * * *

(4) *PSQ reserve.* (See § 679.21(e)(3)(i)(A) and (b)(1)(iv))

* * * * *

■ 6. In § 679.64, revise paragraph (a)(3) to read as follows:

§ 679.64 Harvesting sideboard limits in other fisheries.

(a) * * *

(3) *How will AFA catcher/processor sideboard limits be managed?* The Regional Administrator will manage groundfish harvest limits and PSC bycatch limits for AFA catcher/processors through directed fishing closures in fisheries established under paragraph (a)(1) of this section in accordance with the procedures set out in §§ 679.20(d)(1)(iv) and 679.21(b)(4)(iii).

* * * * *

■ 7. In § 679.91, revise paragraphs (d)(1) and (3) to read as follows:

§ 679.91 Amendment 80 Program annual harvester privileges.

* * * * *

(d) * * *

(1) *Amount of Amendment 80 halibut PSC for the Amendment 80 sector.* The amount of halibut PSC limit for the Amendment 80 sector for each calendar year is specified in Table 35 to this part. That halibut PSC is then assigned to Amendment 80 cooperatives and the Amendment 80 limited access fishery pursuant to paragraphs (d)(2) and (3) of this section. If one or more Amendment 80 vessels participate in the Amendment 80 limited access fishery, the halibut PSC limit assigned to the Amendment 80 sector will be reduced pursuant to paragraph (d)(3) of this section.

* * * * *

(3) *Amount of Amendment 80 halibut PSC assigned to the Amendment 80 limited access fishery.* The amount of Amendment 80 halibut PSC assigned to the Amendment 80 limited access fishery is equal to the amount of halibut PSC assigned to the Amendment 80 sector, as specified in Table 35 to this part, subtracting the amount of Amendment 80 halibut PSC assigned as CQ to all Amendment 80 cooperatives as determined in paragraph (d)(2)(iv) of this section, multiplied by 80 percent.

* * * * *

§§ 679.20, 679.23, 679.24, 679.25, and 679.26 [Amended]

■ 8. At each of the locations shown in the "Location" column, remove the phrase indicated in the "Remove" column and replace it with the phrase indicated in the "Add" column for the number of times indicated in the "Frequency" column.

Location	Remove	Add	Frequency
§ 679.20(d)(2)	§ 679.21(b)	§ 679.21(a)	1
§ 679.23(f)	§ 679.21(b)	§ 679.21(a)	1
§ 679.23(g)(3)	§ 679.21(b)	§ 679.21(a)	1
§ 679.24(c)(2)(ii)(A)	§ 679.21(b)	§ 679.21(a)	1
§ 679.24(c)(2)(ii)(B)	§ 679.21(b)	§ 679.21(a)	1
§ 679.24(c)(3)	§ 679.21(b)	§ 679.21(a)	1
§ 679.24(c)(4)	§ 679.21(b)	§ 679.21(a)	1
§ 679.25(a)(2)(ii)(A)	§ 679.21(b)	§ 679.21(a)	1
§ 679.26(d)(2)	§ 679.21(b)	§ 679.21(a)	1

■ 9. Revise table 35 to part 679 to read as follows:

TABLE 35 TO PART 679—APPORTIONMENT OF CRAB PSC AND HALIBUT PSC BETWEEN THE AMENDMENT 80 AND BSAI TRAWL LIMITED ACCESS SECTORS

Fishery	Halibut PSC limit in the BSAI (mt)	Zone 1 Red king crab PSC limit . . .	*C. opilio* crab PSC limit (COBLZ) . . .	Zone 1 *C. bairdi* crab PSC limit . . .	Zone 2 *C. bairdi* crab PSC limit . . .
		as a percentage of the total BSAI trawl PSC limit after allocation as PSQ.			
Amendment 80 sector	1,745	49.98	49.15	42.11	23.67
BSAI trawl limited access.	745	30.58	32.14	46.99	46.81

■ 10. Revise table 40 to part 679 to read as follows:

TABLE 40 TO PART 679—BSAI HALIBUT PSC SIDEBOARD LIMITS FOR AFA CATCHER/PROCESSORS AND AFA CATCHER VESSELS

In the following target species categories as defined in § 679.21(b)(1)(iii) and (e)(3)(iv) . . .	The AFA catcher/ processor halibut PSC sideboard limit in metric tons is . . .	The AFA catcher vessel halibut PSC sideboard limit in metric tons is . . .
All target species categories	286	N/A
Pacific cod trawl	N/A	887
Pacific cod hook-and-line or pot	N/A	2
Yellowfin sole	N/A	101
Rock sole/flathead sole/“other flatfish” [1]	N/A	228
Turbot/Arrowtooth/Sablefish	N/A	0
Rockfish [2]	N/A	2
Pollock/Atka mackerel/“other species”	N/A	5

[1] “Other flatfish” for PSC monitoring includes all flatfish species, except for halibut (a prohibited species), Greenland turbot, rock sole, flathead sole, yellowfin sole, and arrowtooth flounder.

[2] Applicable from July 1 through December 31.

[FR Doc. 2016–09680 Filed 4–26–16; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 81, No. 81
Wednesday, April 27, 2016

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

2 CFR Part 1800

RIN 2700–AE29

Federal Regulation Supplement: Revisions to Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards (NASA Case 2015–N030)

AGENCY: National Aeronautics and Space Administration.

ACTION: Proposed rule.

SUMMARY: NASA is proposing to amend the NASA regulation, titled Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards to modify the requirements related to information contained in a Federal award for commercial firms with no cost sharing requirement and to add new or modify existing terms and conditions related to indirect cost charges and access to research results.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before June 27, 2016, to be considered in the formation of a final rule.

ADDRESSES: Submit comments identified by NASA Case 2015–N030, using any of the following methods:

○ *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by entering "NASA Case 2015–N030" under the heading "Enter keyword or ID" and selecting "Search." Select the link "Submit a Comment" that corresponds with "NASA Case 2015–N030." Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "NASA Case 2015–N030" on your attached document.

○ *Email: jennifer.l.richards@nasa.gov.* Include NASA Case 2015–N030 in the subject line of the message.

○ *Fax:* (202) 358–3082.

○ *Mail:* National Aeronautics and Space Administration, Headquarters, Office of Procurement, Contract and Grant Policy Division, Attn: Ms. Jennifer Richards, Room 5M34, 300 E Street SW., Washington, DC 20546–0001.

FOR FURTHER INFORMATION CONTACT: Ms. Jennifer Richards, NASA HQ, Office of Procurement, Contract and Grant Policy Division, Room 5M34, 300 E Street SW., Washington, DC 20456–0001. Telephone 202–358–0047; facsimile 202–358–3082.

SUPPLEMENTARY INFORMATION:

I. Background

NASA is proposing the following changes to NASA regulation Uniform Administrative Requirements, Cost Principles and Audit Requirements for Federal Awards (2 CFR part 1800):

1. Modify the requirement related to information contained in a Federal award for commercial firms with no cost sharing requirement. NASA requirements for information contained in a Federal award can be found at 2 CFR 1800.210, which adopts and supplements 2 CFR 200.210. Title 2 CFR 200.210 includes a list of data elements that must be included in a Federal award, including indirect cost rate for the Federal award (including if the de minimis rate is charged per § 200.414 Indirect (F&A) costs). Although 2 CFR part 200 does not apply to commercial firms, NASA, in its adoption of the regulation at 2 CFR 1800.3, Applicability, added commercial firms with no cost sharing requirement to the list of applicable entities. Therefore, the requirement to include an indirect cost rate on a notice of Federal award is applicable to commercial firms with no cost sharing requirement.
2. Add a new term and condition to address those instances when a recipient has a change in its negotiated indirect cost rate agreement during the period of performance of an award. See 2 CFR 200.56, 200.57, and 200.414 for more information on indirect (facilities & administrative) costs. NASA has discovered that, on occasion, when a recipient's indirect cost rate has changed as a result of a new negotiated indirect cost rate agreement, the change in rate has not always been captured when indirect costs have been charged to NASA. As a result, some recipients have either overcharged or undercharged NASA for indirect costs.
3. Modify an existing term and condition and add a new term and condition to ensure recipients meet requirements associated with, "NASA Plan: Increasing Access to the Results of Scientific Research" (see *http://science.nasa.gov/media/medialibrary/2015/07/08/NASA_Plan_for_increasing_access_to_results_of_federally_funded_research1.pdf*). This plan was issued in response to the Executive Office of the President's, Office of Science and Technology Policy (OSTP) Memorandum for the Heads of Executive Departments and Agencies, dated February 22, 2013, "Increasing Access to the Results of Federally Funded Scientific Research." Through this memorandum, OSTP directed all agencies with more than $100 million in annual research and development expenditures to prepare a plan for improving the public's access to the results of federally funded research. Part A of NASA's plan focuses on digital unclassified scientific research data, which are research data that can be stored digitally and accessed electronically.

To facilitate increased access to such data, NASA has updated its research data policy to require all investigators submitting a research proposal or research project plan to NASA to include a Data Management Plan for managing and providing access to final research data or to state why their data cannot or need not be made publicly available. Part B of the plan focuses on the public access to peer-reviewed scientific research manuscripts. The scope of applicability of this part includes all final peer-reviewed scientific research manuscripts authored or coauthored by investigators funded for this research by NASA-appropriated funds.

II. Analysis

After consideration of feedback from commercial firms expressing concern that indirect cost rates are sensitive financial information which should not be available on documents that could potentially be released to the public, NASA has determined that excluding indirect cost rates from notices of Federal award to commercial firms with no cost sharing requirement is a prudent business decision that protects sensitive financial information.

In order to ensure that the permitted amount of indirect costs is being charged to an award, NASA is proposing a new term and condition requiring recipients that have changes to their indirect cost rate agreement during the period of performance of an award to apply the approved rate to covered direct costs expended during the time frame of the rate agreement, even if the agreement is not on file with NASA. This will prevent NASA from overpaying or underpaying for indirect charges and ensure recipients are receiving what they are legally allowed. To address the NASA plan requirements for awardees from non-NASA organizations that publish scientific research or compile digital datasets resulting from research, development, and technology programs, NASA is proposing the following revisions:

- Modify an existing term and condition, 2 CFR 1800.902 Technical Publications and Reports, to add a requirement for awardees with research and research-related awards to follow additional reporting requirements at 2 CFR 1800.930 Access to Research Results.
- Add a new term and condition requiring recipients to comply with their approved Data Management Plan submitted with their proposal, and as modified upon agreement by the recipient and NASA from time to time during the course of the period of performance. In addition, this new term and condition will ensure that any Final Peer-Reviewed Manuscripts are submitted to the NASA-designated repository, currently the PubMed Central system at *www.ncbi.nlm.nih.gov,* within one year of peer-review or publication by a journal, whichever is earlier. Furthermore, it will ensure that any publisher's agreements entered into by an awardee will allow for the awardee to comply with these requirements including submission of Final Peer-Reviewed Manuscripts to the NASA-designated repository, currently the PubMed Central system, with sufficient rights to permit such repository to use such Final Peer-Reviewed Manuscript in its normal course, including rights to permit users to download XML and plain text formats. Finally, the grantee agrees to be responsible for, and defend NASA against, any royalties, fees, or other costs claimed against NASA or for which NASA may be held liable as a consequence of awardee failing to comply with the foregoing and include in annual and final reports a list of Final Peer-Reviewed Manuscripts covered by this term and condition.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This proposed rule is not a major rule under 5 U.S.C. 804.

IV. Paperwork Reduction Act

This proposed rule contains information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C chapter 35; however, these changes to 2 CFR part 1800 do not impose additional information collection requirements to the paperwork burden previously approved under OMB Control Number 2700–0092, entitled Financial Assistant Awards/Grants and Cooperative Agreements.

List of Subjects in 2 CFR Part 1800

Government financial assistance.

Manuel Quinones,

NASA Federal Register Liaison.

Accordingly, 2 CFR part 1800 is proposed to be amended as follows:

PART 1800—UNIFORM ADMINISTRATIVE REQUIREMENTS, COST PRINCIPLES, AND AUDIT REQUIREMENTS FOR FEDERAL AWARDS

■ 1. The authority citation for 2 CFR part 1800 continues to read as follows:

Authority: 51 U.S.C. 20113(e), Pub. L. 97–258, 96 Stat. 1003 (31 U.S.C. 6301 *et seq.*), and 2 CFR part 200.

■ 2. Revise § 1800.210 to read as follows:

§ 1800.210 Information contained in a Federal award.

NASA waives the requirement for the inclusion of indirect cost rates on any notice of Federal award for commercial firms with no cost sharing requirement. The terms and conditions for NASA may be found at Appendix B of this Part and *https://prod.nais.nasa.gov/pub/pub_library/srba.*

■ 3. Amend Appendix B to part 1800 by:

■ a. Under 1800.902 Technical Publications and Reports, adding paragraph (a)(4); and

■ b. Adding 1800.929 Indirect Costs and 1800.930 Access to Research Results.

The additions read as follows:

Appendix B to Part 1800—Terms and Conditions

* * * * *

1800.902 Technical Publications and Reports

* * * * *

(a) * * *

* * * * *

(4) For research and research-related awards, see additional reporting requirements at 1800.930 Access to Research Results.

* * * * *

1800.929 Indirect Costs

Prescription —The Grant Officer shall include this term and condition in all awards with indirect costs, excluding those awards using the 10% de minimis rate.

Indirect Costs

If during the course of this award, the approved indirect cost rate is revised, changed or removed, that rate must be applied, as allowed, to the covered direct costs that are expended during the time frame of that rate agreement. Any corrections, either up or down, to the approved budget submitted with the awarded application must be reflected in the awardees' records of costs and should be audited as such.

(End of Term and Condition)

1800.930 Access to Research Results

Prescription—The Grant Officer shall include this term and condition in all research and research-related awards.

Access to Research Results

(a) This award is subject to the requirements of the, "NASA Plan: Increasing Access to the Results of Scientific Research," which covers public access to digital scientific data and peer-reviewed publications. For purposes of this term and condition, the following definitions apply:

(1) Awardee: Any recipient of a NASA grant or cooperative agreement, its investigators, and subrecipient (subaward or contract as defined in 2 CFR part 200.92 and 200.22, respectively) at any level.

(2) Final Peer-Reviewed Manuscript: The final text version of a peer-reviewed article disclosing the results of scientific research which is authored or co-authored by the Awardee or funded, in whole or in part, with funds from a NASA award, that includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article.

(b) The recipient shall:

(1) Comply with their approved Data Management Plan submitted with its proposal, and as modified upon agreement by the recipient and NASA from time to time

during the course of the period of performance.

(2) Ensure that any Final Peer-Reviewed Manuscript is submitted to the NASA-designated repository, currently the PubMed Central system at *www.ncbi.nlm.nih.gov.* Ensure that the Final Peer-Reviewed Manuscript is submitted to PubMed Central within one year of peer-review or publication by a journal, whichever is earlier.

(3) Ensure that any publisher's agreements entered into by an Awardee will allow for the Awardee to comply with these requirements including submission of Final Peer-Reviewed Manuscripts to the NASA-designated repository, as listed in the above bullet, with sufficient rights to permit such repository to use such Final Peer-Reviewed Manuscript in its normal course, including rights to permit users to download XML and plain text formats.

(4) Agree to be responsible for, and defend NASA against, any royalties, fees, or other costs claimed against NASA or for which NASA may be held liable as a consequence of Awardee failing to comply with the foregoing. Include in annual and final reports a list of Final Peer-Reviewed Manuscripts covered by this term and condition.

(End of Term and Condition)

[FR Doc. 2016–09625 Filed 4–26–16; 8:45 am]

BILLING CODE 7510–13–P

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 532

RIN 3206–AN37

Prevailing Rate Systems; Redefinition of the Asheville, NC, and Charlotte, NC, Appropriated Fund Federal Wage System Wage Areas

AGENCY: U.S. Office of Personnel Management.

ACTION: Proposed rule with request for comments.

SUMMARY: The U.S. Office of Personnel Management (OPM) is issuing a proposed rule that would redefine the geographic boundaries of the Asheville, NC, and Charlotte, NC, appropriated fund Federal Wage System (FWS) wage areas. The proposed rule would redefine Alexander and Catawba Counties, NC, from the Charlotte wage area to the Asheville wage area. These changes are based on a recent consensus recommendation of the Federal Prevailing Rate Advisory Committee (FPRAC) to best match the counties proposed for redefinition to a nearby FWS survey area. There are no FWS employees stationed in Alexander or Catawba Counties.

DATES: We must receive comments on or before May 27, 2016.

ADDRESSES: You may submit comments, identified by "RIN 3206–AN37," using any of the following methods:

Federal eRulemaking Portal: http:// www.regulations.gov. Follow the instructions for submitting comments.

Mail: Brenda L. Roberts, Deputy Associate Director for Pay and Leave, Employee Services, U.S. Office of Personnel Management, Room 7H31, 1900 E Street NW., Washington, DC 20415–8200.

Email: pay-leave-policy@opm.gov.

FOR FURTHER INFORMATION CONTACT: Madeline Gonzalez, (202) 606–2858; email *pay-leave-policy@opm.gov*; or FAX: (202) 606–4264.

SUPPLEMENTARY INFORMATION: OPM is issuing a proposed rule that would redefine the geographic boundaries of the Asheville, NC, and Charlotte, NC, appropriated fund FWS wage areas. The proposed rule would redefine Alexander and Catawba Counties, NC, from the Charlotte wage area to the Asheville wage area.

OPM considers the following regulatory criteria under 5 CFR 532.211 when defining FWS wage area boundaries:

(i) Distance, transportation facilities, and geographic features;

(ii) Commuting patterns; and

(iii) Similarities in overall population, employment, and the kinds and sizes of private industrial establishments.

In addition, OPM regulations at 5 CFR 532.211 do not permit splitting Metropolitan Statistical Areas (MSAs) for the purpose of defining a wage area, except in very unusual circumstances.

Alexander, Burke, Caldwell, and Catawba Counties, NC, comprise the Hickory-Lenoir-Morganton, NC, MSA. The Hickory-Lenoir-Morganton MSA is split between the Asheville, NC, and Charlotte, NC, wage areas. Burke and Caldwell Counties are part of the area of application of the Asheville wage area and Alexander and Catawba Counties are part of the area of application of the Charlotte wage area.

Based on an analysis of the regulatory criteria for Caldwell County, the core county in the Hickory-Lenoir-Morganton MSA, the entire Hickory-Lenoir-Morganton MSA would be defined to the Asheville wage area. When measuring to cities, the distance criterion does not favor one wage area more than another. When measuring to host installations, the distance criterion favors the Asheville wage area more than the Charlotte wage area. The commuting patterns criterion does not favor one wage area more than another. Caldwell County resembles the Asheville survey area more than the Charlotte survey area in terms of the overall population and employment and the kinds and sizes of private industrial establishments criteria.

Based on this analysis, we believe Caldwell County is appropriately defined to the Asheville wage area. OPM regulations at 5 CFR 532.211 permit splitting MSAs only in very unusual circumstances. There appear to be no unusual circumstances that would permit splitting the Bloomsburg-Berwick MSA. To comply with OPM regulations not to split MSAs, Alexander and Catawba Counties would be redefined to the Asheville wage area. The remaining county in the Hickory-Lenoir-Morganton MSA, Burke County, is already defined to the Asheville wage area. There are currently no FWS employees working in Alexander and Catawba Counties.

FPRAC, the national labor-management committee responsible for advising OPM on matters concerning the pay of FWS employees, recommended this change by consensus. This change would be effective on the first day of the first applicable pay period beginning on or after 30 days following publication of the final regulations.

Regulatory Flexibility Act

I certify that these regulations would not have a significant economic impact on a substantial number of small entities because they would affect only Federal agencies and employees.

List of Subjects in 5 CFR Part 532

Administrative practice and procedure, Freedom of information, Government employees, Reporting and recordkeeping requirements, Wages.

U.S. Office of Personnel Management.

Beth F. Cobert,

Acting Director.

Accordingly, the U.S. Office of Personnel Management is proposing to amend 5 CFR part 532 as follows:

PART 532—PREVAILING RATE SYSTEMS

■ 1. The authority citation for part 532 continues to read as follows:

Authority: 5 U.S.C. 5343, 5346; § 532.707 also issued under 5 U.S.C. 552.

Appendix C to Subpart B of Part 532—Appropriated Fund Wage and Survey Areas

■ 2. Appendix C to subpart B is amended by revising the wage area listings for the proposed rule that would redefine the geographic boundaries of the wage areas to read as follows:

* * * * *

NORTH CAROLINA

Asheville

Survey Area

North Carolina:
  Buscombe
  Haywood
  Henderson
  Madison
  Transylvania

Area of Application. Survey area plus:

North Carolina:
  Alexander
  Avery
  Burke
  Caldwell
  Catawba
  Cherokee
  Clay
  Graham
  Jackson
  McDowell
  Macon
  Mitchell
  Polk
  Rutherford
  Swain
  Yancey

* * * * *

Charlotte

Survey Area

North Carolina:
  Cabarrus
  Gaston
  Mecklenburg
  Rowan
  Union

Area of Application. Survey area plus:

North Carolina:
  Anson
  Cleveland
  Iredell
  Lincoln
  Stanly
  Wilkes
South Carolina:
  Chester
  Chesterfield
  Lancaster
  York

* * * * *

[FR Doc. 2016–09701 Filed 4–26–16; 8:45 am]

BILLING CODE 6325–39–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Doc. No. AMS–NOP–15–0052; NOP–15–12PR]

RIN 0581–AD43

National Organic Program (NOP); Sunset 2016 Amendments to the National List; Correction

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule; correction.

SUMMARY: This document contains a correction to the proposed rule which was published on December 16, 2015 (80 FR 78150). In the proposed rule, the Regulatory Information Number (RIN) appears as RIN 0581–AD39. This number is incorrect. The correct number is 0581–AD43. This document corrects the proposed rule.

DATES: April 27, 2016.

FOR FURTHER INFORMATION CONTACT: Valerie Frances, Standards Division, email: *valerie.frances@ams.usda.gov.* Telephone: (202) 720–3252; Fax: (202) 260–9151.

Correction

In proposed rule FR Doc. 2015–31380, beginning at page 78150 of the issue of December 16, 2015, make the following corrections:

On page 78150, in the first column in the heading and the first line of the second column under the **ADDRESSES** caption, correct the RIN to read "0581–AD43".

Dated: April 22, 2016.

Elanor Starmer,

Administrator, Agricultural Marketing Service.

[FR Doc. 2016–09838 Filed 4–26–16; 8:45 am]

BILLING CODE P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Parts 701 and 721

RIN 3133–AE54

Federal Credit Union Occupancy, Planning, and Disposal of Acquired and Abandoned Premises; Incidental Powers

AGENCY: National Credit Union Administration (NCUA).

ACTION: Proposed rule.

SUMMARY: As part of NCUA's Regulatory Modernization Initiative, the NCUA Board (Board) is issuing for public comment a proposed rule to amend its regulation governing federal credit union (FCU) occupancy, planning, and disposal of acquired and abandoned premises, and its regulation regarding incidental powers. To provide regulatory relief to FCUs, the proposal eliminates a requirement in the current occupancy rule (formerly known as the fixed assets rule) that an FCU must plan for, and eventually achieve, *full* occupancy of acquired premises.

The proposal generally retains the current regulatory timeframes for *partial* occupancy. However, it modifies the definition of "partially occupy" to mean occupation and use, on a full-time basis, of at least fifty percent of the premises by the FCU, or by a combination of the FCU and a credit union service organization (CUSO) in which the FCU has a controlling interest in accordance with Generally Accepted Accounting Principles (GAAP).

The proposal also amends the excess capacity provision in NCUA's incidental powers rule to clarify that an FCU may lease or sell excess capacity in its *facilities,* but it need not anticipate that such excess capacity will be fully occupied by the FCU in the future. However, the sale or lease of excess capacity in *equipment or services,* including employee-sharing and data processing for third parties, continues to be limited to circumstances where an FCU reasonably anticipates that such excess capacity will be taken up by the future expansion of services to members.

DATES: Comments must be received on or before June 27, 2016.

ADDRESSES: You may submit comments by any of the following methods (Please send comments by one method only):

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *NCUA Web site: https://www.ncua.gov/regulation-supervision/Pages/rules/proposed.aspx.* Follow the instructions for submitting comments.
- *Email:* Address to *regcomments@ncua.gov.* Include "[Your name] Comments on Notice of Proposed Rulemaking for Parts 701 and 721, FCU Occupancy, Planning, and Disposal of Acquired and Abandoned Premises; Incidental Powers" in the email subject line.
- *Fax:* (703) 518–6319. Use the subject line described above for email.
- *Mail:* Address to Gerard Poliquin, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.

- *Hand Delivery/Courier:* Same as mail address.

Public Inspection: You may view all public comments on NCUA's Web site at *http://www.ncua.gov/Legal/Regs/Pages/PropRegs.aspx* as submitted, except for those we cannot post for technical reasons. NCUA will not edit or remove any identifying or contact information from the public comments submitted. You may inspect paper copies of comments in NCUA's law library at 1775 Duke Street, Alexandria, Virginia 22314, by appointment weekdays between 9 a.m. and 3 p.m. To make an appointment, call (703) 518–6546 or send an email to *OGCMail@ncua.gov.*

FOR FURTHER INFORMATION CONTACT: Pamela Yu, Senior Staff Attorney, Office of General Counsel, at the above address or telephone (703) 518–6540, or Jacob McCall, Program Officer, Office of Examination and Insurance, at the above address or telephone (703) 518–6360.

SUPPLEMENTARY INFORMATION:

I. Background
II. Summary of the Proposed Rule
III. Regulatory Procedures

I. Background

Section 107(4) of the Federal Credit Union Act (FCU Act) authorizes an FCU to purchase, hold, and dispose of property necessary or incidental to its operations.[1] NCUA's occupancy rule (formerly referred to as the fixed assets rule) interprets and implements this provision of the FCU Act by establishing occupancy, planning, and disposal requirements for acquired and abandoned premises. The rule also prohibits certain transactions to avoid conflicts of interest in the acquisition or lease of FCU premises.[2]

Over the past several years, the Board has proposed and adopted several regulatory amendments to modernize § 701.36.[3] Most recently, in July 2015, the Board approved a final rule to eliminate the five percent aggregate limit on investments in fixed assets for FCUs with $1,000,000 or more in assets and to streamline the partial occupancy requirements. Public comment in response to these recent amendments has been generally supportive of the Board's ongoing efforts to provide regulatory relief to FCUs in this area. However, commenters have continued to ask for more regulatory relief to provide FCUs with greater flexibility in the management of property necessary or incidental to FCU operations. In particular, commenters have strongly advocated the elimination of regulatory occupancy requirements, especially the requirement for full occupancy.

In general, commenters have maintained that the FCU Act does not expressly mandate specific timeframes for occupancy or otherwise prescribe occupancy requirements for FCU premises. Thus, commenters have urged the Board to liberalize NCUA's occupancy rules.[4] For example, commenters have said that NCUA should not set a specific time period for full occupancy; that FCU boards and management should determine the best timeframe in which to fully develop property; and that the full occupancy requirement should be eliminated entirely.[5] Commenters have also suggested that NCUA should replace the "full" occupancy requirement with a "significant" or "substantial" occupancy requirement, defined as fifty-one percent occupancy.[6]

In addition, commenters urging NCUA to reconsider its position on full occupancy have indicated that it oftentimes makes sense for a credit union to own a building and lease out part or all of the building to help offset the cost of property ownership.[7] Commenters have argued that prescriptive occupancy requirements reduce access to commercial space and limit an FCU's ability to acquire space in the most cost-effective manner. As an example, commenters have noted that some local zoning or mixed-use ordinances, city entitlements, or other use requirements may require a portion of the property to be dedicated to retail business.[8] Commenters have also posited that generating long-term income from FCU premises would generate value for the FCU's membership.[9]

The Board has carefully considered the numerous comments received on this subject since at least 2013.[10] The Board also has reconsidered the regulatory position that the limited authority for FCUs to invest in property granted by Section 107(4) of the FCU Act means that an FCU may not hold real property indefinitely without fully occupying the premises. Accordingly, as discussed in more detail below, the Board is proposing to eliminate from the current occupancy rule the requirement that an FCU must plan for, and eventually achieve, *full* occupancy of its premises. The proposal generally retains the current regulatory timeframes for *partial* occupancy and the related waiver provisions, including those finalized in July 2015.[11] However, the current definition of "partially occupy" is modified in the proposal to reflect that an FCU need not fully occupy premises, but the FCU (or a combination of the FCU and a CUSO in which the FCU has a controlling interest in accordance with GAAP) must utilize at least fifty percent of the premises on a full-time basis within the required timeframe to achieve partial occupancy. For consistency, the proposal also amends the excess capacity provision in the incidental powers rule and makes technical and conforming amendments[12] to reflect the proposed policy change regarding full occupancy for FCU premises.

The proposed rule is discussed in greater detail below.

II. Summary of the Proposed Rule

A. Occupancy rule

Under the current rule, if an FCU acquires premises for future expansion and does not fully occupy them within one year, it must have an FCU board resolution in place by the end of that year with definitive plans for full occupation.[13] For purposes of the rule, "premises" means any office, branch office, suboffice, service center, parking lot, other facility, or real estate where the FCU transacts or will transact business.[14] The current rule does not set a specific time period within which an

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[1] 12 U.S.C. 1757(4).

[2] 12 CFR 701.36.

[3] 78 FR 57250 (Sept. 18, 2013); 79 FR 46727 (Aug. 11, 2014); 80 FR 16595 (Mar. 30, 2015); 80 FR 45844 (Aug. 3, 2015).

[4] 80 FR 45844 (Aug. 3, 2015).

[5] 80 FR 16595, 16599 (Mar. 30, 2015).

[6] *Id.*

[7] 80 FR 45844 (Aug. 3, 2015).

[8] 80 FR 16595, 16599 (Mar. 30, 2015).

[9] *Id.*

[10] In fact, requests for relief from the full occupancy requirement date back to at least 2004. *See* 69 FR 58039, 58041 (Sept. 29, 2004) ("Several commenters believe NCUA should reduce or eliminate the rule's requirements for both partial and full occupation, but particularly for full occupation. These commenters contend it is difficult for a credit union to obtain a building or lease space that is a perfect fit for the credit union's current and near term plans and the rule's occupation requirements restrict credit union growth and may be anticompetitive. One commenter cites the perceived difficulty rural and low-income credit unions have in finding appropriate office space, and another cites the perceived difficulty a continuing credit union in a merger has in balancing reduced staffing needs with the buildings it inherits in a merger.")

[11] 80 FR 45844 (Aug. 3, 2015).

[12] For example, the proposed rule generally removes references to "future expansion" and other language that implies an FCU must plan for and achieve full occupancy of its premises.

[13] 12 CFR 701.36(c)(1). Under the current rule, the reasonableness of an FCU's plan for full occupation is evaluated through the examination process and based upon such factors as the defensibility of projection assumptions, the operational and financial feasibility of the plan, and the overall suitability of the plan relative to the FCU's field of membership.

[14] 12 CFR 701.36(b).

FCU must achieve full occupation of premises acquired for future expansion. However, partial occupancy of the premises is required within a reasonable period, but no later than six years after the date of acquisition, regardless of whether the premises are improved or unimproved.[15] Partial occupancy must be sufficient to show, among other things, that the FCU will fully occupy the premises within a reasonable time and consistent with its plan for the premises.[16]

The occupancy requirements in the current rule have a statutory basis, but full occupancy of FCU premises is not expressly or specifically mandated by statute. Section 107(4) of the FCU Act authorizes an FCU to purchase, hold, and dispose of property *necessary or incidental to its operations.*[17] NCUA has long held that the limited authority granted by this provision means that an FCU may not hold, or lease to unrelated third parties, real property indefinitely without fully occupying the premises.[18]

After further consideration, however, the Board believes the language in Section 107(4) of the FCU Act supports an interpretation that provides FCUs' with more flexibility to acquire and hold real property. Accordingly, the Board has reconsidered its current approach of ensuring that FCU investment in and use of real property is consistent with the FCU Act by requiring FCUs to fully occupy premises. Section 107(4) neither explicitly mentions nor expressly requires full occupancy of FCU property. Accordingly, the Board proposes to eliminate the full occupancy and related planning requirements in the current occupancy rule. Specifically, the proposed rule deletes the requirement in current § 701.36(c)(1) that, if an FCU acquires premises for future expansion and does not fully occupy them within one year, it must have a board resolution in place by the end of that year with definitive plans for full occupation.

While this proposed change represents a departure from the Board's previous interpretation of Section 107(4), it is both reasonable and consistent with the requirements of the FCU Act. The United States Supreme Court has emphasized that an "initial agency interpretation is not instantly carved in stone," and "to engage in informed rulemaking, [an agency] must consider varying interpretations and the wisdom of its policy on a continuing basis," indicating that an agency may change its interpretive position on the statutes it administers.[19] In light of the continuing requests from commenters for relief from the full occupancy requirement, the proposed change is required to avoid unnecessarily imposing undue hardship on FCUs that may have difficulty realizing their growth potential and member service strategies under the current rule.

The Board emphasizes, however, that it maintains its current view that there is no authority in the FCU Act for an FCU to invest in real estate for speculative purposes or to otherwise engage in real estate activities that do not generally support its purpose of providing financial services to its members. The statute is clear that any property acquired or held by an FCU must be "necessary or incidental to its operations."[20] NCUA has stated consistently that an FCU may only invest in property it intends to use to transact credit union business or in property that supports its internal operations or member services.[21]

Although the Board's position on *full* occupancy has evolved, it continues to read the FCU Act as requiring that an FCU may purchase or hold property only for a permissible purpose or activity; that is, to support the FCU's provision of financial services to its members. As the Board noted in the preamble to the July 2015 final rule, the requirement for an FCU to partially occupy its acquired premises within a specified timeframe is intended to function as a reasonable safeguard against speculative real estate investments or other real estate activities that are not permitted for FCUs under the FCU Act.[22] Making speculative investments in real property exceeds an FCU's authority and can lead to safety and soundness problems. Making speculative investments in real property increases an FCU's exposure to market factors unrelated to financial services. As well, managing unoccupied real property or commercial leases creates operational risk exposures which are significantly different from those related to managing authorized financial services permissible for FCUs. By maintaining the requirement that FCUs must partially occupy real property, NCUA reduces the opportunity for speculative investment and helps FCUs align their real property investment decisions with the operational needs of the FCU and its members.

Requiring an FCU to fully occupy its acquired premises may, under certain circumstances: (1) Hinder its ability to obtain cost-effective office space necessary to serve its members; (2) restrict its growth; or (3) place it at a competitive disadvantage. However, without a reasonable occupancy requirement, there is little to inhibit an FCU from: (1) Speculating on real property with the sole intent of realizing a profit from its future sale; (2) acting as a property developer or full-time landlord; or (3) otherwise venturing into real estate activities that are beyond the scope of its authority under Section 107(4). Accordingly, the Board has determined that an FCU must at least partially occupy each of its acquired real property. For both legal and safety and soundness reasons, the proposed rule retains the requirement that an FCU premises, including unimproved property, must be partially occupied within six years from the date of its acquisition. An FCU may apply for a waiver if it is not able to achieve partial occupancy of its premises within six years.[23]

Under the current rule, "partially occupy" means occupation, on a full-time basis, of a portion of the premises that is: (1) Consistent with the FCU's usage plan for the premises; (2) significant enough that the FCU is deriving practical utility from the occupied portion relative to the scope of the usage plan; and (3) sufficient to show that the FCU will fully occupy the premises within a reasonable time.[24] The Board proposes to modify the current definition of "partial occupancy" to eliminate references to the current requirement to plan for full occupancy (usage plan) and the need to show that the FCU will fully occupy the premises. Additionally, the Board proposes to amend that definition to emphasize that at least fifty percent of FCU premises must be occupied and used, on a full-time basis, by the FCU or a combination of the FCU and a CUSO in which the FCU has a controlling interest in accordance with GAAP.[25] Occupancy of FCU premises with third-party vendors or CUSOs in which the FCU does not maintain a controlling interest will not count towards the fifty percent partial occupancy requirement because these entities operate at the direction of other owners and may not be obligated to primarily support the FCU that acquired the premises or to primarily serve that FCU's members. The proposed definition, which incorporates elements from the current rule's definition of full occupancy,[26] will ensure that any property acquired or held by an FCU is primarily utilized for a purpose that is necessary or incidental to its operations, as required by the FCU Act.

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[15] 12 CFR 701.36(c)(2).

[16] 12 CFR 701.36(b).

[17] 12 U.S.C. 1757(4) (emphasis added).

[18] 69 FR 58039, 58041 (Sept. 29, 2004).

[19] *Chevron* v. *Natural Resources Defense Council*, 467 U.S. 837, 863–864 (1984). The Supreme Court has also found that an agency is entitled to *Chevron* deference if it reverses an earlier interpretation. *See e.g., Rust* v. *Sullivan*, 500 U.S. 173 (1991); *National Cable & Telecommunications Ass'n* v. *Brand X Internet Services*, 545 U.S. 967 (2005).

[20] 12 U.S.C. 1757(4).

[21] *See* 43 FR 58176, 58178 (Dec. 13, 1978) ("Part 107(4) of the Federal Credit Union Act provides that a credit union may purchase, hold, and dispose of property necessary or incidental to its operations. Retaining a piece of property whose only purpose is to provide office space to other entities is clearly not necessary or incidental to the Federal credit union's operations. Further, investing in, or holding, property with the intent of realizing a profit from appreciation at a future sale is also outside the powers of a Federal credit union."); 69 FR 58039, 58041 (Sept. 29, 2004) ("Federal credit unions are chartered for the purpose of providing financial services to their members and it is not permissible for them to engage in real estate activities that do not support that purpose.")

[22] 80 FR 45844 (Aug. 3, 2015).

[23] 12 CFR 701.36(c)(2).

[24] 12 CFR 701.36(b).

B. Incidental powers.

The Board recognizes that in planning for future expansion, FCUs should be permitted to sell or lease their excess capacity as a matter of good business practice.[27] The incidental powers rule permits an FCU to sell or lease its excess capacity with respect to its property and services.[28] Under that rule, excess capacity refers to the excess use or capacity remaining in FCU facilities, equipment, or services.[29] An FCU's sale or lease of excess capacity, for example, may involve leasing excess office space, sharing employees, or using data processing systems to process information for third parties.[30] However, while an FCU has the authority under the rule to obtain income by selling or leasing excess capacity in its facilities, equipment, or services to third parties, that authority is subject to the following conditions: (1) The facilities, equipment, or services must have been acquired by an FCU, in good faith, for the purpose of providing financial services to its members; and (2) the FCU must reasonably anticipate that the excess capacity will be taken up by the future expansion of services to its members.[31]

To conform to the above proposed amendments to the occupancy rule, the Board proposes to amend the incidental powers rule regarding the sale or lease of excess capacity by removing the condition that excess capacity in FCU facilities must eventually be fully occupied by the FCU. The Board continues to believe, however, that the sale or lease of excess capacity in equipment or services, including employee-sharing and data processing for third parties, should be limited to circumstances where an FCU reasonably anticipates that the excess capacity will be taken up by the future expansion of services to its members.

In adopting the excess capacity provision in the incidental powers rule, the Board reasoned in 2001 that "[t]he sale of excess capacity offers FCUs the opportunity to provide financial services to its members, even though member demand for the services does not initially meet the FCU's capacity." [32] However, the Board also noted:

> NCUA has consistently held the position that an FCU has limited authority in the leasing of fixed assets and the sale of excess data processing capacity. FCUs are not in the business of providing others with data processing capacity or any other service that is not within their express or incidental powers; rather, they are cooperative financial institutions organized to provide financial services to their members.[33]

While the Board has reconsidered its position with respect to requiring full occupancy of FCU facilities, the Board maintains its view that FCUs are not, and should not be, in the business of providing third parties with data processing capacity or other equipment or services outside their express or incidental powers. Accordingly, under this proposal, an FCU's authority to sell or lease excess capacity in equipment and services continues to be conditioned on the FCU's reasonable anticipation that its members will eventually fully utilize the excess capacity.

III. Regulatory Procedures

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires that, in connection with a notice of proposed rulemaking, an agency prepare and make available for public comment an initial regulatory flexibility analysis that describes the impact of a proposed rule on small entities. A regulatory flexibility analysis is not required, however, if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities (defined for purposes of the RFA to include credit unions with assets less than $100 million) and publishes its certification and a short, explanatory statement in the **Federal Register** together with the rule. The proposed rule would provide regulatory relief by eliminating the need to develop a plan for full occupancy. However, FCUs currently have limited flexibility to purchase real estate with excess capacity. NCUA certifies that the proposed rule will not have a significant economic impact on a substantial number of small credit unions.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) applies to rulemakings in which an agency by rule creates a new paperwork burden on regulated entities or modifies an existing burden.[34] For purposes of the PRA, a paperwork burden may take the form of either a reporting or a recordkeeping requirement, both referred to as information collections. The proposed rule provides regulatory relief to FCUs by eliminating the requirement that, if an FCU does not fully occupy premises acquired for future expansion within one year, it must have a board resolution in place by the end of that year with definitive plans for full occupation. The proposed rule does not impose new paperwork burdens. The proposed rule would relieve FCUs from the current requirement to have a board-approved plan for full occupation of its premises.

According to NCUA estimates, approximately 15 FCUs are required to develop a plan for full occupation premises each year. Accordingly, the reduction to existing paperwork burdens that would result from the proposal is analyzed below:

Estimate of the reduced burden by eliminating the full occupancy planning requirement.

Estimated FCUs: 15.

Frequency of waiver request: Annual.

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[25] FASB Accounting Standards Update (ASU) 805 defines controlling interest as "the ability of an entity to direct the policies and management that guide the ongoing activities of another entity so as to increase its benefits and limit its losses from that other entity's activities." More generally, controlling interest is majority interest or any other ownership interest which entitles the owner to direct the activities of the CUSO.

[26] 12 CFR 701.36(c)(1).

[27] 66 FR 40845, 40851 (Aug. 6, 2001).

[28] The incidental powers rule defines an incidental powers activity as one that is necessary or requisite to enable an FCU to carry on effectively the business for which it is incorporated. An activity meets the definition of an incidental powers activity if it: (1) Is convenient or useful in carrying out the mission or business of credit unions consistent with the FCU Act; (2) is the functional equivalent or logical outgrowth of activities that are part of the mission or business of credit unions; and (3) involves risks similar in nature to those already assumed as part of the business of credit unions. 12 CFR 721.2.

[29] 12 CFR 721.3(e).

[30] *Id.*

[31] *Id.*

[32] 66 FR 40845, 40851 (Aug. 6, 2001).

[33] *Id.*

[34] 44 U.S.C. 3507(d); 5 CFR part 1320.

Reduced hour burden: 15 hours.

15 FCUs × 15 hours = 225 hours reduced burden.

In accordance with the requirements of the PRA, NCUA intends to obtain a modification of its OMB Control Number, 3133–0040, to support these changes. NCUA is submitting a copy of the proposed rule to OMB, along with an application for a modification of the OMB Control Number.

The PRA and OMB regulations require that the public be provided an opportunity to comment on the paperwork requirements, including an agency's estimate of the burden of the paperwork requirements. The Board invites comment on: (1) Whether the paperwork requirements are necessary; (2) the accuracy of NCUA's estimates on the burden of the paperwork requirements; (3) ways to enhance the quality, utility, and clarity of the paperwork requirements; and (4) ways to minimize the burden of the paperwork requirements.

Comments should be sent to the NCUA Contact and the OMB Reviewer listed below:

NCUA Contact: Dawn Wolfgang, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. 703–837–2861, Email: *OCIOPRA@ncua.gov.*

OMB Contact: Office of Management and Budget, ATTN: Desk Officer for the National Credit Union Administration, Office of Information and Regulatory Affairs, Washington, DC 20503.

C. Executive Order 13132

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on state and local interests. NCUA, an independent regulatory agency, as defined in 44 U.S.C. 3502(5), voluntarily complies with the executive order to adhere to fundamental federalism principles. Because the occupancy and incidental powers regulations apply only to FCUs, the proposed rule would not have a substantial direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. As such, NCUA has determined that this rule does not constitute a policy that has federalism implications for purposes of the executive order.

D. Assessment of Federal Regulations and Policies on Families

NCUA has determined that this rule will not affect family well-being within the meaning of Section 654 of the Treasury and General Government Appropriations Act of 1999.[35]

List of Subjects

12 CFR Part 701

Credit unions, Reporting and recordkeeping requirements.

12 CFR Part 721

Credit unions, functions, implied powers.

By the National Credit Union Administration Board, on April 21, 2016.

Gerard Poliquin,

Secretary of the Board.

For the reasons stated above, NCUA proposes to amend 12 CFR parts 701 and 721 as follows:

PART 701—ORGANIZATION AND OPERATION OF FEDERAL CREDIT UNIONS

■ 1. The authority for part 701 continues to read as follows:

Authority: 12 U.S.C. 1752(5), 1757, 1765, 1766, 1781, 1782, 1787, 1789; Title V, Pub. L. 109–351, 120 Stat. 1966.

■ 2. Amend the title of § 701.36 and amend §§ 701.36(a) and (b) to read as follows:

§ 701.36 Federal credit union occupancy and disposal of acquired and abandoned premises.

(a) *Scope.* Section 107(4) of the Federal Credit Union Act (12 U.S.C. 1757(4)) authorizes a federal credit union to purchase, hold, and dispose of property necessary or incidental to its operations. This section interprets and implements that provision by establishing occupancy and disposal requirements for acquired and abandoned premises, and by prohibiting certain transactions. This section applies only to federal credit unions.

(b) * * *

Abandoned premises means premises previously used to transact credit union business but no longer used for that purpose. It also means premises originally acquired to transact future credit union business but no longer intended for that purpose.

* * * * *

Partially occupy means occupation and use, on a full-time basis, of at least fifty percent of each of the premises by the federal credit union, or the federal credit union and a credit union service organization in which the federal credit union has a controlling interest in accordance with Generally Accepted Accounting Principles (GAAP).

* * * * *

■ 3. Remove § 701.36(c)(1); redesignate § 701.36(c)(2) as § 701.36(c)(1) and amend it to read as follows:

(c) *Premises not currently used to transact credit union business.* (1) If a federal credit union acquires premises, including unimproved land or unimproved real property, it must partially occupy each of them within a reasonable period, but no later than six years after the date of acquisition. NCUA may waive the partial occupation requirements. To seek a waiver, a federal credit union must submit a written request to its Regional Office and fully explain why it needs the waiver. The Regional Director will provide the federal credit union a written response, either approving or disapproving the request. The Regional Director's decision will be based on safety and soundness considerations.

■ 4. Redesignate § 701.36(c)(3) as § 701.36(c)(2).

PART 721—INCIDENTAL POWERS

■ 5. The authority for part 721 continues to read as follows:

Authority: 12 U.S.C. 1757(17), 1766 and 1789.

■ 6. Amend § 721.3 to read as follows:

§ 721.3 What categories of activities are preapproved as incidental powers necessary or requisite to carry on a credit union's business?

* * * * *

(a) * * *

(b) * * *

(c) * * *

(d) * * *

(e) *Excess capacity.* Excess capacity is the excess use or capacity remaining in facilities, equipment, or services that you properly invested in or established, in good faith, with the intent of serving your members or supporting your business operations. You may sell or lease the excess capacity in facilities, such as office space and other premises. You may sell or lease the excess capacity in equipment or services, such as employees and data processing, if you reasonably anticipate that the excess capacity will be taken up by the future expansion of services to your members.

* * * * *

[FR Doc. 2016–09867 Filed 4–26–16; 8:45 am]

BILLING CODE 7535–01–P

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[35] Public Law 105–277, 112 Stat. 2681 (1998).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–6123; Directorate Identifier 2016–CE–007–AD]

RIN 2120–AA64

Airworthiness Directives; Schempp-Hirth Flugzeugbau GmbH Gliders

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for Schempp-Hirth Flugzeugbau GmbH Models Discus-2a, Discus-2b, Discus-2c, Discus 2cT, Ventus-2a, and Ventus-2b gliders. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as insufficient overlap of the airbrake panels. We are issuing this proposed AD to require actions to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by June 13, 2016.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Schempp-Hirth Flugzeugbau GmbH, Krebenstrasse 25, 73230 Kirchheim/Teck, Germany; telephone: +49 7021 7298–0; fax: +49 7021 7298–199; email: *info@schempp-hirth.com*; Internet: *http://www.schempp-hirth.com.* You may review this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6123; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Jim Rutherford, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4165; fax: (816) 329–4090; email: *jim.rutherford@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2016–6123; Directorate Identifier 2016–CE–007–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued AD No.: 2016–0027, dated February 9, 2016 (referred to after this as "the MCAI"), to correct an unsafe condition for the specified products. The MCAI states:

> Operational experience shows that, under certain conditions, the overlap between the two airbrake panels can be insufficient and the panels can interlock.
>
> This condition, if not corrected, could lead to blockage of the airbrakes, possibly resulting in reduced control of the (powered) sailplane.
>
> To address this potential unsafe condition, Schempp-Hirth Flugzeugbau GmbH issued TN 349–39, 360–29, 825–55 and 863–22 (single document, hereafter referred to as 'the TN' in this AD), to provide inspection instructions to verify the correct overlap between the two affected airbrake panels.
>
> For the reason described above, this AD requires a one-time inspection of the overlap of the affected airbrake panels and, depending on findings, accomplishment of applicable corrective action(s).

You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6123.

Related Service Information Under 1 CFR Part 51

Schempp-Hirth Flugzeugbau GmbH has issued Technical Note No. 349–39, 360–29, 825–55, 863–22; dated January 29, 2016 (published as a single document), and Arbeitsanweisung (English translation: Working instructions) for Technische Mitteilung Nr. (English translation: Technical Note No.) 349–39, 360–29, 825–55, 863–22, Ausgabe (English translation: Issue) 1, Datum (English translation: Dated) January 22, 2016. The service information describes procedures for inspection of the overlap of the airbrake panels and, if necessary, replacement of the airbrake panels. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this NPRM.

FAA's Determination and Requirements of the Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with this State of Design Authority, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Costs of Compliance

We estimate that this proposed AD will affect 86 products of U.S. registry. We also estimate that it would take about 2 work-hours per product to comply with the basic requirements of this proposed AD.

Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $14,620, or $170 per product.

In addition, we estimate that any necessary follow-on actions would take about 4 work-hours and require parts costing $100, for a cost of $440 per product. We have no way of determining the number of products that may need these actions.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a "significant regulatory action" under Executive Order 12866,

(2) Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new AD:

Schempp-Hirth Flugzeugbau GmbH: Docket No. FAA–2016–6123; Directorate Identifier 2016–CE–007–AD.

(a) Comments Due Date

We must receive comments by June 13, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the following Schempp-Hirth Flugzeugbau GmbH model and serial number gliders, certificated in any category:

(1) Model Discus-2a, serial numbers 1 through 253;

(2) Model Discus-2b, serial numbers 1 through 255;

(3) Model Discus-2c, serial numbers 1 through 61;

(4) Model Discus 2cT, serial numbers 1 through 127;

(5) Model Ventus-2a, serial numbers 1 through 178; and

(6) Model Ventus-2b, serial numbers 1 through 175.

(d) Subject

Air Transport Association of America (ATA) Code 27: Flight Controls.

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as insufficient overlap of the airbrake panels. We are issuing this proposed AD to require actions to address the unsafe condition on these products. We are issuing this AD to prevent interlocking of the airbrake panels, which could lead to blockage of the airbrakes and possible loss of control.

(f) Actions and Compliance

Unless already done, do the following actions in paragraphs (f)(1) and (f)(2) of this AD:

(1) Within the next 40 days after the effective date of this AD, inspect the overlap of the airbrake panels for a minimum overlap of at least 3 millimeters following Action 1 in Schempp-Hirth Flugzeugbau GmbH Technische Mitteilung Nr. (English translation: Technical Note No.) 349–39, 360–29, 825–55, 863–22, dated January 29, 2016 (published as a single document); and Action 1 in the associated Arbeitsanweisung (English translation: Working instructions) for Technische Mitteilung Nr. (English translation: Technical Note No.) 349–39, 360–29, 825–55, 863–22, Ausgabe (English translation: issue) 1, Datum (English translation: dated) January 22, 2016.

Note 1 to paragraph (f)(1) and (f)(2) of this AD: This service information contains German to English translation. The EASA used the English translation in referencing the document. For enforceability purposes, we will refer to the Schempp-Hirth Flugzeugbau GmbH service information as it appears on the document.

(2) If, during the inspection required in paragraph (f)(1) of this AD, the overlap on the airbrake panels is found to be less than 3 millimeters, before further flight, install eccentric bushings and make adjustments following Action 2 in Schempp-Hirth Flugzeugbau GmbH Technische Mitteilung Nr. (English translation: Technical Note No.) 349–39, 360–29, 825–55, 863–22, dated January 29, 2016 (published as a single document); and Action 2 in the associated Arbeitsanweisung (English translation: Working instructions) for Technische Mitteilung Nr. (English translation: Technical Note No.) 349–39, 360–29, 825–55, 863–22, Ausgabe (English translation: issue) 1, Datum (English translation: dated) January 22, 2016.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Jim Rutherford, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4165; fax: (816) 329–4090; email: *jim.rutherford@faa.gov.* Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(h) Related Information

Refer to MCAI European Aviation Safety Agency (EASA) AD No.: 2016–0027, dated February 9, 2016, for related information. You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–6123. For service information related to this AD, contact Schempp-Hirth Flugzeugbau GmbH, Krebenstrasse 25, 73230 Kirchheim/Teck, Germany; telephone: +49 7021 7298–0; fax: +49 7021 7298–199; email: *info@schempp-hirth.com*; Internet: *http://www.schempp-hirth.com.* You may review this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on April 15, 2016.

Melvin Johnson,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–09435 Filed 4–26–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–5596; Directorate Identifier 2015–NM–121–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede Airworthiness Directive (AD) 2014–12–06, for certain Airbus Model A300 B4–600, B4–600R, and F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes (collectively called Model A300–600 series airplanes); and Airbus Model A310 series airplanes. AD 2014–12–06 currently requires inspections of the external area of the aft cargo door sill beam for cracking, and repair if necessary. Since we issued AD 2014–12–06, we have determined it is necessary to require that high frequency eddy current (HFEC) inspections be performed repetitively. This proposed AD would mandate the previously optional terminating HFEC inspection, and require that it be done repetitively. We are proposing this AD to detect and correct fatigue cracking of the cargo door sill beam, lock fitting, and torsion box plate. Failure of one or more of these components could result in the loss of the door locking function and, subsequently, complete loss of the cargo door in flight with the risk of rapid decompression.

DATES: We must receive comments on this proposed AD by June 13, 2016.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Airbus SAS, Airworthiness Office—EAW, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–5596; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–2125; fax 425–227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2016–5596; Directorate Identifier 2015–NM–121–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

On June 4, 2014, we issued AD 2014–12–06, Amendment 39–17867 (79 FR 34403, June 17, 2014) ("AD 2014–12–06"). AD 2014–12–06 requires actions intended to address an unsafe condition on certain Airbus Model A300 B4–600, B4–600R, and F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes (collectively called Model A300–600 series airplanes); and Airbus Model A310 series airplanes.

Since we issued AD 2014–12–06, we have determined it is necessary to require that the HFEC inspections be performed repetitively.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2015–0150, dated July 23, 2015 (referred to after this as the Mandatory Continuing Airworthiness Information, or "the MCAI"), to correct an unsafe condition for certain Airbus Model A300 B4–600, B4–600R, and F4–600R series airplanes, and Model A300 C4–605R Variant F airplanes (collectively called Model A300–600 series airplanes); and Airbus Model A310 series airplanes. The MCAI states:

> During accomplishment of Maintenance Review Board Report (MRBR) task 531625–01–1 on an A300–600 aeroplane having accumulated more than 25,000 flight cycles (FC) since aeroplane first flight, multiple fatigue cracks were found on the following parts:
>
> —Aft cargo door sill beam Part Number (P/N) A53973085210
> —Lock fitting P/N A53978239002
> —Torsion box plate P/N A53973318206.
>
> Prompted by these findings, a stress analysis was performed during which it was discovered that there is no dedicated scheduled maintenance task to inspect the affected area for fatigue damage.
>
> This condition, if not detected and corrected, could lead to failure of multiple lock fittings, possibly resulting in loss of the cargo door in flight and consequent explosive decompression of the aeroplane.
>
> To address this unsafe condition, Airbus issued Alert Operators Transmission (AOT) A53W005–14 providing instructions for inspection of the affected area.
>
> Consequently, EASA issued Emergency AD 2014–0097–E [FAA AD 2014–12–06, Amendment 39–17867 (79 FR 34403, June 17, 2014)] to require repetitive ultrasonic (US) inspections or detailed inspections (DET) of the aft cargo door sill beam external area, and/or a one-time High Frequency Eddy Current (HFEC) inspection of the aft cargo door sill beam internal structure and, depending on findings, accomplishment of corrective action(s).
>
> Since that [EASA] AD was issued, the results of further analysis have indicated that repetitive HFEC inspections need to be introduced.

For the reasons described above, this [EASA] AD retains the requirements of EASA AD 2014–0097–E, which is superseded, and requires repetitive HFEC inspections of the concerned areas. The first HFEC inspection terminates the repetitive US/DET inspections.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–5596.

Related Service Information Under 1 CFR Part 51

Airbus has issued Service Bulletin A300–53–6179, dated December 12, 2014; and Service Bulletin A310–53–2139, dated December 12, 2014. The service information describes procedures for repetitive HFEC inspections of the cargo door sill beam, lock fitting, and torsion box plate.

Airbus has also issued AOT A53W005–14, Revision 01, dated April 29, 2014. The service information describes procedures for doing an ultrasonic inspection or detailed inspection of the aft cargo door sill beam external area for cracking.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of these same type designs.

Costs of Compliance

We estimate that this proposed AD affects 75 airplanes of U.S. registry.

The actions required by AD 2014–12–06, and retained in this proposed AD, take about 12 work-hours per product, at an average labor rate of $85 per work-hour. Based on these figures, the estimated cost of the actions that are required by AD 2014–12–06 and retained in this AD is $1,020 per product.

We also estimate that it would take about 1 work-hour per product to comply with the reporting requirements of this proposed AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $6,374, or $85 per product.

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this proposed AD.

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB control number. The control number for the collection of information required by this AD is 2120–0056. The paperwork cost associated with this AD has been detailed in the Costs of Compliance section of this document and includes time for reviewing instructions, as well as completing and reviewing the collection of information. Therefore, all reporting associated with this AD is mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at 800 Independence Ave. SW., Washington, DC 20591, ATTN: Information Collection Clearance Officer, AES–200.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing AD 2014–12–06, Amendment 39–17867 (79 FR 34403, June 17, 2014), and adding the following new AD:

Airbus: Docket No. FAA–2016–5596; Directorate Identifier 2015–NM–121–AD.

(a) Comments Due Date

We must receive comments by June 13, 2016.

(b) Affected ADs

This AD replaces AD 2014–12–06, Amendment 39–17867 (79 FR 34403, June 17, 2014) ("AD 2014–12–06").

(c) Applicability

This AD applies to the airplanes identified in paragraphs (c)(1), (c)(2), (c)(3), (c)(4), and (c)(5) of this AD, certificated in any category, all manufacturer serial numbers on which Airbus Modification 05438 has been embodied in production, except those on which Airbus Modification 12046 has been embodied in production.

(1) Airbus Model A300 B4–601, B4–603, B4–620, and B4–622 airplanes.

(2) Airbus Model A300 B4–605R and B4–622R airplanes.

(3) Airbus Model A300 F4–605R and F4–622R airplanes.

(4) Airbus Model A300 C4–605R Variant F airplanes.

(5) Airbus Model A310–203, –204, –221, –222, –304, –322, –324, and –325 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Reason

This AD was prompted by reports of fatigue cracks on the cargo door sill beam, lock fitting, and torsion box plate. We are issuing this AD to detect and correct fatigue cracking of the cargo door sill beam, lock fitting, and torsion box plate, which could result in the loss of the door locking function and subsequently, complete loss of the cargo door in flight with the risk of rapid decompression.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Retained Inspection With Revised Service Information

This paragraph restates the requirements of paragraph (g)(1) of AD 2014–12–06 with revised service information: Within the compliance time identified in paragraph (g)(1), (g)(2), or (g)(3) of this AD, as applicable, do an ultrasonic inspection or detailed inspection of the aft cargo door sill beam external area for cracking, in accordance with Airbus Alert Operators Transmission (AOT) A53W005–14, dated April 22, 2014; or Airbus AOT A53W005–14, Revision 01, dated April 29, 2014. Repeat the inspection thereafter at intervals not to exceed 275 flight cycles. As of the effective date of this AD, only Airbus AOT A53W005–14, Revision 01, dated April 29, 2014, may be used to comply with the requirements of this paragraph.

(1) For airplanes that have accumulated 30,000 flight cycles or more since the airplane's first flight as of July 2, 2014 (the effective date of AD 2014–12–06): Within 50 flight cycles after July 2, 2014.

(2) For airplanes that have accumulated 18,000 flight cycles or more, but fewer than 30,000 flight cycles since the airplane's first flight as of July 2, 2014 (the effective date of AD 2014–12–06): Within 275 flight cycles after July 2, 2014.

(3) For airplanes that have accumulated fewer than 18,000 flight cycles since the airplane's first flight as of July 2, 2014 (the effective date of AD 2014–12–06): Before exceeding 18,275 flight cycles since the airplane's first flight.

(h) Retained Optional Terminating Action, With Revised Service Information

This paragraph restates the provisions of paragraph (h) of AD 2014–12–06, with revised service information. Accomplishment of high frequency eddy current (HFEC) inspection for cracking, in accordance with Airbus AOT A53W005–14, dated April 22, 2014; or Airbus AOT A53W005–14, Revision 01, dated April 29, 2014, terminates the repetitive inspections required by paragraph (g) of this AD for that airplane. If any cracking is found during the HFEC inspection, before further flight, repair using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA).

(i) Retained Reporting Requirement, With Revised Service Information

This paragraph restates the provisions of paragraph (i) of AD 2014–12–06, with revised service information. Submit a report of the findings (both positive and negative) of the inspection required by paragraph (g) of this AD to Airbus, as specified in paragraph 7.,"Reporting," of Airbus AOT A53W005–14, dated April 22, 2014; or Airbus AOT A53W005–14, Revision 01, dated April 29, 2014, at the applicable time specified in paragraph (i)(1) or (i)(2) of this AD. The report must include inspection results, including no findings.

(1) If the inspection was done on or after the effective date of this AD: Submit the report within 30 days after the inspection.

(2) If the inspection was done before the effective date of this AD: Submit the report within 30 days after the effective date of this AD.

(j) Definition of Airplane Groups

Paragraphs (k)(1), (k)(2), and (k)(3) of this AD refer to airplane groups, as identified in paragraphs (j)(1), (j)(2), and (j)(3) of this AD.

(1) Airplanes on which a HFEC inspection was accomplished as specified in Airbus AOT A53W005–14.

(2) Airplanes on which no HFEC inspection was accomplished as specified in Airbus AOT A53W005–14, and that have accumulated more than 18,000 total flight cycles as of the effective date of this AD.

(3) Airplanes on which no HFEC inspection accomplished as specified in Airbus AOT A53W005–14, that have accumulated 18,000 total flight cycles or fewer as of the effective date of this AD.

(k) New Repetitive HFEC Inspections and Repair

At the applicable time specified in paragraph (k)(1), (k)(2), or (k)(3) of this AD, do an HFEC inspection for fatigue cracking of the cargo door sill beam, lock fitting, and torsion box plate, in accordance with Airbus Service Bulletin A300–53–6179, dated December 12, 2014; or Airbus Service Bulletin A310–53–2139, dated December 12, 2014, as applicable. Repeat the HFEC inspection thereafter at intervals not to exceed 4,600 flight cycles.

(1) For airplanes identified in paragraph (j)(1) of this AD: Inspect within 4,600 flight cycles after the most recent HFEC inspection specified in Airbus AOT A53W005–14.

(2) For airplanes identified in paragraph (j)(2) of this AD: Inspect within 2,000 flight cycles after the effective date of this AD.

(3) For airplanes identified in paragraph (j)(3) of this AD: Inspect before exceeding 13,000 total flight cycles since the airplane's first flight, or within 2,000 flight cycles after the effective date of this AD, whichever occurs later.

(l) Corrective Action

If any crack is found during any inspection required by paragraph (g) or (k) of this AD: Before further flight, repair using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the EASA; or Airbus's EASA DOA.

(m) Terminating Action for HFEC Inspections

For any airplane identified in paragraphs (j)(2) and (j)(3) of this AD, accomplishment of the initial inspection required by paragraph (k) of this AD terminates the repetitive inspections required by paragraph (g) of this AD.

(n) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–2125; fax 425–227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov*. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer:* As of the effective date of this AD, for any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the EASA; or Airbus's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Reporting Requirements:* A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

(4) *Required for Compliance (RC):* Except as required by paragraph (l) of this AD: If any service information contains procedures or tests that are identified as RC, those

procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(o) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) European Aviation Safety Agency (EASA) Airworthiness Directive 2015–0150, dated July 23, 2015, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–5596.

(2) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAW, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on April 15, 2016.

Victor Wicklund,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–09641 Filed 4–26–16; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 228

[FRL–9945–52–Region 1]

Ocean Disposal; Designation of a Dredged Material Disposal Site in Eastern Region of Long Island Sound; Connecticut

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) proposes to designate one dredged material disposal site, the Eastern Long Island Sound Disposal Site (ELDS) located offshore from New London, Connecticut, for the disposal of dredged material from harbors and navigation channels in eastern Long Island Sound in the states of Connecticut and New York. This action is necessary to provide a long-term, open-water dredged material disposal site as an alternative for the possible future disposal of such material. This disposal site designation is subject to various restrictions designed to support the goal of reducing or eliminating the disposal of dredged material in Long Island Sound.

While EPA is currently proposing to designate the ELDS as its preferred alternative, EPA also has concluded, based on the analysis in the Draft Supplemental Environmental Impact Statement for the Designation of Dredged Material Disposal Site(s) in Eastern Long Island Sound, Connecticut and New York (DSEIS), that two other alternatives, the Niantic Bay and Cornfield Shoals disposal sites (NBDS and CSDS), or portions thereof, could potentially be designated in addition to, or instead of, the ELDS. EPA is not currently recommending the NBDS and CSDS as preferred alternatives, but is inviting public comments on the option of designating one or both of these sites instead of, or as a complement to, the ELDS.

DATES: Comments must be received on or before June 27, 2016. EPA will hold four public hearings to receive comments on the proposed rule. The first two will be held on May 25, 2016, from 1–3 p.m. at the Suffolk County Community College Culinary Arts Center, 20 East Main St., Riverhead, NY 11901, and from 5:30–7:30 p.m. at the Mattituck-Laurel Library, 13900 Main Rd., Mattituck, NY 11952. The second two will be held on May 26, 2016, from 1–3 p.m. and from 5–7 p.m. at the University of Connecticut—Avery Point, Academic Building, Room 308, 1084 Shennecossett Rd., Groton, CT 06340. Registration will begin 30 minutes before each of the four hearings.

ADDRESSES: Written comments should be sent to *ELIS@epa.gov.*

FOR FURTHER INFORMATION CONTACT: Ms. Jean Brochi, U.S. Environmental Protection Agency, New England Regional Office, 5 Post Office Square, Suite 100, Mail Code: OEP06–1, Boston, MA 02109–3912, telephone: (617) 918–1536, fax number: (617) 918–0536; email address: *Brochi.Jean@epa.gov* or *ELIS@epa.gov.*

SUPPLEMENTARY INFORMATION: The supporting document for this site designation is the DSEIS. The DSEIS is considered supplemental because it updates and builds on analyses that were conducted for the 2005 Long Island Sound Environmental Impact Statement that supported the designation of the Central and Western Long Island Sound dredged material disposal sites. This document is available for public inspection at the following locations:

1. EPA Web site: *https://www.epa.gov/ocean-dumping/dredged-material-management-long-island-sound.*
2. Regulations.gov: Docket No. EPA–R01–OW–2016–0239.
3. In person: EPA Region 1 Library, 5 Post Office Square, Boston, MA 02109.

Organization of this document. The following outline is provided to aid in locating information in this preamble.

I. Background
II. Purpose and Need
III. Potentially Affected Entities
IV. Disposal Site Descriptions
  A. Eastern Long Island Sound Disposal Site
  B. Niantic Bay Disposal Site
  C. Cornfield Shoals Disposal Site
V. Compliance With Statutory and Regulatory Authorities
  A. Marine Protection, Research, and Sanctuaries Act and Clean Water Act
  B. National Environmental Policy Act
  C. Coastal Zone Management Act
  D. Endangered Species Act
  E. Magnuson-Stevens Fishery Conservation and Management Act
VI. Restrictions
VII. Proposed Action
VIII. Supporting Documents
IX. Statutory and Executive Order Reviews

I. Background

Section 102(c) of the Marine Protection, Research, and Sanctuaries Act of 1972 (MPRSA), as amended, 33 U.S.C. 1412, gives the Administrator of EPA the authority to designate sites where ocean disposal may be permitted. On October 1, 1986, the Administrator delegated the authority to designate ocean dredged material disposal sites to the Regional Administrator of the Region in which the sites are located. The preferred alternative site, ELDS, and the other two alternatives, NBDS and CSDS, are all located within Connecticut state waters, which is within the area assigned to EPA Region 1, *see* 40 CFR 1.7(b)(1); therefore the designation of one or more of these sites is being proposed pursuant to the EPA Region 1 Administrator's delegated authority.

EPA regulations (40 CFR 228.4(e)(1)) promulgated under the MPRSA require, among other things, that EPA designate ocean disposal sites by promulgation in 40 CFR 228. Designated ocean disposal sites are codified at 40 CFR 228.15.

The primary authorities that govern the aquatic disposal of dredged material in the United States are the MPRSA, 33 U.S.C. 1401 *et seq.*, and the Clean Water Act of 1972, 33 U.S.C. 1251 *et seq.* (CWA). While the CWA does not apply specifically to an EPA designation of a long-term dredged material disposal site under the MPRSA, future federal and non-federal projects involving dredged material disposal in Long Island Sound will require both a section 404 permit as well as a State Water Quality Certification pursuant to section 401 of the CWA. In 1980, the MPRSA was amended to add Section 106(f) to the statute. 33 U.S.C. 1416(f). This provision is commonly referred to as the "Ambro Amendment," named after its author, Congressman Jerome Ambro. MPRSA section 106(f), 33 U.S.C. 1416(f), was itself amended in 1990. Under this provision, the disposal of dredged material in Long Island Sound from both federal projects (*i.e.*, projects carried out by the USACE Civil Works Program or the actions of other federal agencies) and from non-federal projects generating more than 25,000 cubic yards of material must satisfy the requirements of both CWA section 404 and the MPRSA. Disposal from non-federal projects generating less than 25,000 cubic yards of material, however, are subject only to CWA section 404.

This rule proposes to designate the ELDS for open-water disposal of dredged material. While EPA is currently proposing the designation of the ELDS as its preferred alternative, EPA also has concluded, based on the analysis in the DSEIS, that two other alternatives, the Niantic Bay and Cornfield Shoals disposal sites (NBDS and CSDS), or portions thereof, could potentially be designated in addition to, or instead of, the ELDS. All three sites are described in detail in section IV, Disposal Site Descriptions.

EPA has conducted the disposal site designation process consistent with the requirements of the MPRSA, the National Environmental Policy Act (NEPA), the Coastal Zone Management Act (CZMA), and other relevant statutes and regulations. The site designations are intended to be effective for an indefinite period of time.

It is important to understand that the designation of a dredged material disposal site by EPA does not by itself authorize the disposal at that site of dredged material from any particular dredging project. For example, designation of the ELDS would only make that site available to receive dredged material from a specific project if no environmentally preferable, practicable alternative for managing that dredged material exists, and if analysis of the dredged material indicates that it is suitable for open-water disposal. *See* 40 CFR 227.1(b), 227.2 and 227.3; 40 CFR part 227, subparts B and C.

Thus, each proposed dredging project will be evaluated on a case-by-case basis to determine whether there are practicable, environmentally preferable alternatives to open-water disposal (*i.e.*, whether there is a need for open-water disposal). In addition, the dredged material from each proposed disposal project will be subjected to MPRSA and/or CWA sediment testing requirements to determine its suitability for possible open-water disposal at an approved site. Alternatives to open-water disposal that will be considered include upland disposal and beneficial uses such as beach nourishment. If environmentally preferable, practicable disposal alternatives exist, open-water disposal will not be allowed. EPA also will not approve dredged material for open-water disposal if it determines that the material has the potential to cause unacceptable adverse effects to the marine environment or human health. The review process for proposed disposal projects is discussed in more detail below and in the DSEIS.

Dredged material disposal sites designated by EPA under the MPRSA are subject to detailed management and monitoring protocols to track site conditions and prevent the occurrence of unacceptable adverse effects. EPA and the USACE typically share responsibility for the management and monitoring of these disposal sites. The management and monitoring protocols for the ELDS are described in the Site Management and Monitoring Plan (SMMP) that is incorporated in the DSEIS as Appendix I. *See* 33 U.S.C. 1412(c)(3). EPA is authorized to close or limit the use of these sites to further disposal activity if their use causes unacceptable adverse impacts to the marine environment or human health.

II. Purpose and Need

As described in the DSEIS, the purpose of EPA's proposed action is to determine whether one or more environmentally sound open-water dredged material disposal sites should be authorized for future long-term use in the eastern Long Island Sound region and, if so, to designate the site or sites accordingly and consistent with applicable law. The need for this effort derives from the following facts: (1) There are currently no disposal sites designated for long-term use in the eastern Long Island Sound region; (2) the two currently used sites in this region are only authorized for use until December 23, 2016; (3) periodic dredging is necessary to maintain safe navigation and marine commerce, and dredged material disposal is necessary when practicable alternative means of managing the material are not available; (4) EPA determined, based on the evaluation of projected dredging needs over a 30-year planning horizon and alternatives to open-water disposal conducted for the USACE's DMMP, that there are dredging and dredged material disposal/handling needs that exceed the available disposal/handling capacity in the eastern region of Long Island Sound; and (5) the MPRSA requires an EPA designation for any long-term dredged material disposal site.

In addition, the closest designated sites outside the eastern Long Island Sound region (and outside the "Zone of Siting Feasibility," or ZSF, which is discussed in Section 1.3 of the DSEIS), are the Central Long Island Sound Disposal Site (CLDS) and the Rhode Island Sound Disposal Site (RISDS), which are 29.9 nautical miles (nmi) and 51.4 nmi, respectively, from the Saybrook Outer Bars at the mouth of the Connecticut River. The Saybrook Outer Bars is the southernmost project in the Connecticut River dredging center, which is the largest dredging center in the eastern Long Island Sound region. The Western Long Island Sound Disposal Site (WLDS) is even farther to the west than the CLDS, lying 58.4 nmi from the Connecticut River dredging center (DMMP, Section 5.3).

While the CLDS, WLDS, and RISDS have all been determined to be environmentally sound sites for receiving suitable dredged material, proposing to use any of them for suitable dredged material from the eastern region of Long Island Sound would be problematic and EPA would consider them to be options of last resort. Indeed, EPA does not consider the WLDS to be a truly viable option for eastern Long Island Sound material given how distant it is and given the fact that if material was being hauled long distance to the west from the eastern region of the Sound, the material would be taken to the CLDS and not hauled even farther to the WLDS. At the same time, using the CLDS or RISDS (not to mention the WLDS) would greatly increase the transport distance for, and duration of, open-water disposal for dredging projects from the eastern Long Island Sound region. This, in turn, would greatly increase the cost of such projects and would likely render many dredging projects too expensive to conduct, thus threatening safe navigation and interfering with marine recreation and commerce. Furthermore, the greater transport distance would also be environmentally detrimental in that it would entail greater energy use, increased air emissions, and increased risk of spills and short dumps (DSEIS, Section 2.1). Regarding air emissions, increased hauling distances may require using larger scows with more powerful tug boats, which would use more fuel and cause more emission of air pollutants.

As determined by the USACE through the development of its recently completed Long Island Sound Dredged Material Management Plan (DMMP), and described in the DSEIS (Section 2.3 and Tables 2–2 and 2–3), dredging in eastern Long Island Sound is projected to generate approximately 22.6 million cubic yards (mcy) of dredged material over the next 30 years, including 17.9 mcy from Connecticut ports and harbors and 4.7 mcy from ports and harbors in New York. Of the total amount of 22.6 mcy, approximately 13.5 mcy are projected to be fine-grained sediment that meets MPRSA and CWA standards for aquatic disposal (*i.e.*, "suitable" material), and 9.1 mcy are projected to be coarse-grained sand that also meets MPRSA and CWA standards for aquatic disposal (*i.e.*, also "suitable" material). In addition, the DMMP estimates that approximately 80,900 cy of material from eastern Long Island Sound will be fine-grained sediment that does not meet MPRSA and CWA standards for aquatic disposal (*i.e.*, "unsuitable" material).

Although Rhode Island is included in the ZSF for an eastern Long Island Sound dredged material disposal site—the ZSF is described later in section V, Compliance with Statutory and Regulatory Authorities—the volume of material estimated to come from two Rhode Island dredging centers (Block Island and South-Central/Southeast Washington County) located within the ZSF in Rhode Island is not included in the total amount of material estimated to come from the eastern portion of the Sound. This is because these dredging centers are closer to the RISDS. In addition, much of the dredged material from these two dredging centers is sand and will end up being used beneficially to nourish beaches.

The DMMP also estimates the total dredging needs for the entire Long Island Sound region at 52.9 mcy, meaning the central and western regions are projected to generate approximately 30.3 mcy of dredged material over the 30-year planning horizon (DMMP, Section 4.7 and Table 4.1). Of the total of 30.3 mcy, 20.9 mcy are projected to be fine-grained sediment that meets MPRSA and CWA standards for aquatic disposal (*i.e.*, "suitable" material), 6.1 mcy are projected to be course-grained sand that also would be suitable for open-water disposal, and 3.3 mcy is projected to be fine-grained sediment unsuitable for open-water disposal. This leaves a total of 27 mcy of dredged material that could be suitable for open-water disposal, although EPA expects most, if not all, of the 6.1 mcy of sand would be used beneficially. The combined capacity of the CLDS and WLDS is approximately 40 mcy, which is enough to handle the 27 mcy from those regions. Those sites, however, neither have the capacity nor were intended also to meet the dredging needs of the eastern Long Island Sound region, which, as stated above, has been estimated to be approximately 22.6 mcy of suitable material (which, when added to the 27 mcy of suitable material from the central and western regions, amounts to a total of 49.6 mcy of suitable material from all of Long Island Sound). Furthermore, the distances from mouth of the Connecticut River to the CLDS and WLDS are 29.9 nmi and 58.4 nmi, respectively. Thus, both sites are outside the ZSF for the eastern Long Island Sound Region and for the reasons discussed above, neither would be a viable as a long-term solution for dredged material from the eastern Long Island Sound region, even if the CLDS could conceivably be used for material from the eastern Sound in an emergency situation.

The DMMP also included a detailed assessment of alternatives to open-water disposal and determined that, while all the sand generated in this region should be able to be used beneficially to nourish beaches, there are not practicable alternatives to open-water disposal with sufficient capacity to handle the projected volume of fine-grained sediment. As described in section VI, Restrictions, and in the proposed rule itself, there will be restrictions on the use of all Long Island Sound dredged material disposal sites that are designed to facilitate and promote the use of practicable alternatives to open-water disposal whenever available, but one or more designated open-water disposal sites are needed in eastern Long Island Sound.

EPA designation of a long-term dredged material disposal site(s) provides environmental benefits. First, when use of a site under the USACE short-term site selection authority is due to expire, designation by EPA is the only way to authorize continued use of that site, even if the site is environmentally suitable or even environmentally preferable to all other sites. With the NLDS and CSDS closing in December 2016, EPA's site designation studies were designed to determine whether or not these or any other sites should be designated for continued long-term use. Congress has directed that the disposal of dredged material should take place at EPA-designated sites, rather than USACE-selected sites, when EPA-designated sites are available (*see* MPRSA 103(b)). Thus, Congress has identified a preference for use of EPA-designated sites.

Second, MPRSA criteria for selecting and designating sites require EPA to consider previously used disposal sites or areas, with active or historically used sites given preference in the evaluation (40 CFR 228.5(e)). This preference is intended to concentrate the effects, if any, of disposal practices to small, discrete areas that have already received dredged material, and avoid distributing any effects over a larger geographic area. Finally, EPA designated sites require a SMMP that will help ensure environmentally sound monitoring and management of the sites.

Periodic dredging of harbors and channels and, therefore, dredged material management, are essential for ensuring safe navigation and facilitating marine commerce. This is because the natural processes of erosion and siltation result in sediment accumulation in federal navigation channels, harbors, port facilities, marinas, and other important areas of our water bodies. Unsafe navigational conditions not only threaten public health and safety, but also pose an environmental threat from an increased risk of spills from vessels involved in accidents. Navigation safety is a regulatory requirement for such agencies as the USACE and U.S. Coast Guard.

Economic considerations also contribute to the need for dredging (and the environmentally sound management of dredged material). There are a large number of important navigation-dependent businesses and industries in the eastern Long Island Sound region and Block Island Sound, ranging from shipping (especially the movement of petroleum fuels and the shipping of bulk materials), to recreational boating-related businesses, marine transportation, commercial and recreational fishing, interstate ferry operations, and military navigation, such as that associated with the U.S. Naval Submarine Base in New London. These businesses and industries contribute substantially to the region's economic output, the gross state product (GSP) of the bordering states and tax revenue. Continued access to harbors, berths, and mooring areas is vital to ensuring the continued economic health of these industries, and to preserving the ability of the region to import fuels, bulk supplies, and other commodities at competitive prices. In addition, preserving navigation channels, marinas, harbors, berthing areas, and other marine resources, improves the quality of life for residents and visitors to the eastern Long Island Sound region by facilitating recreational boating and associated activities, such as fishing and sightseeing.

Finally, maintaining these marine areas (*i.e.*, navigation channels, harbors, berthing areas) also is important for homeland security and public safety, as they support the operation of the U.S. Naval Submarine Base and USCG facilities in the region, as well as other governmental entities that operate on the waters of Long Island Sound.

III. Potentially Affected Entities

Entities potentially affected by this proposed action are persons, organizations, or government bodies seeking to dispose of dredged material in waters of eastern Long Island Sound, subject to the requirements of the MPRSA and/or the CWA and their implementing regulations. This proposed rule is expected to be primarily of relevance to: (a) Private parties seeking permits from the USACE to transport more than 25,000 cubic yards of dredged material for the purpose of disposal into the waters of eastern Long Island Sound; (b) the USACE for its own dredged material disposal projects; and (c) other federal agencies seeking to dispose of dredged material in eastern Long Island Sound. Potentially affected entities and categories of entities that may seek to use the proposed dredged material disposal site and would be subject to the proposed rule include:

Category	Examples of potentially affected entities
Federal government	USACE (Civil Works Projects), and other federal agencies.
State, local, and tribal governments	Governments owning and/or responsible for ports, harbors, and/or berths, government agencies requiring disposal of dredged material associated with public works projects.
Industry and general public	Port authorities, shipyards and marine repair facilities, marinas and boatyards, and berth owners.

This table is not intended to be comprehensive, but rather provides a guide for readers regarding the types of entities that could potentially be affected should the proposed rule become a final rule. EPA notes that nothing in this proposed rule alters the jurisdiction or authority of EPA, the USACE, or the types of entities regulated under the MPRSA and/or CWA. Questions regarding the applicability of this proposed rule to a particular entity should be directed to the contact person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

IV. Disposal Site Descriptions

This rule proposes to designate the ELDS for open-water disposal of dredged material for several reasons. First, unlike the other two alternatives (*i.e.*, Cornfield Shoals and portions of the Niantic Bay site), the entire ELDS is a containment site, which would support effective management and monitoring. Second, the NLDS, a part of which makes up part of the ELDS, has been used for dredged material disposal for over 35 years, and monitoring of the site has determined that past and present management practices have been successful in minimizing short-term, long-term, and cumulative impacts to water quality and benthic habitat. Third, designating the ELDS, which includes a portion of the NLDS, would be consistent with USEPA's ocean disposal regulations, which indicate a preference for designating disposal sites in areas that have been used in the past, rather than new, relatively undisturbed areas (40 CFR 228.5(e)). Finally, the capacity of the ELDS is approximately 27 million cy (based on water volume below 59 feet [18 m]), which would be sufficient to meet the dredging needs of the eastern Long Island Sound region for the next 30 years and beyond.

While EPA is currently proposing the designation of the ELDS as its preferred alternative, EPA also has concluded, based on the analysis in the DSEIS, that two other alternatives, the Niantic Bay and Cornfield Shoals disposal sites (NBDS and CSDS), or portions thereof, could potentially be designated in addition to, or instead of, the ELDS. The Niantic Bay alternative, located just to the west of the existing NLDS, contains an area that was historically used (*i.e.*, the NBDS), which is a criterion in the regulations. It also has a capacity of up to 27 million cy (based on water volume below 59 feet [18 m]), which is sufficient to meet the dredging needs of the eastern Long Island Sound region. However, the Niantic Bay site is predominately a transitional area, with a containment area in the northeastern corner, and the remainder of the site being dispersive. EPA is not recommending this site as a preferred alternative at this time primarily because it is not fully a containment site, as is the ELDS site.

The CSDS, located in the western part of eastern Long Island Sound, has been used for dredged material disposal for over 30 years. Because the site is located in a highly dispersive environment, disposal there has been limited to certain types of sediment (*e.g.*, sandy material). Monitoring of the site has determined that past and present management practices have been successful in minimizing short-term, long-term, and cumulative impacts to water quality and benthic habitat from dredged material disposal. Designation of this site in addition to one of the other alternatives would provide a disposal site on both ends of eastern Long Island Sound, which could reduce travel time for tugs/scows transporting dredged material for disposal at the CSDS. This, in turn, could reduce costs and further minimize any risks of spills or short dumps. Due to the high energy and dispersive nature of the area, the site has unlimited capacity, but disposal at the site would be restricted to only certain types of sediments, such as sand, consistent with past practice.

Despite these considerations, EPA does not currently recommend designating the CSDS. Given the site's dispersive characteristics, EPA concludes that the CSDS would not be appropriate to designate as the sole disposal site in eastern Long Island Sound. *See* 40 CFR 228.6(a)(5) and (6). Furthermore, EPA is not proposing to designate the Cornfield Shoals site even as a limited complement to one or more other sites because of the growing opportunities for sand and other dredged sediments to be beneficially used, such as for beach nourishment.

The following site descriptions are based on information in section 3.4.3 of the DSEIS and other support documents. Specifically, Figures 3–9 and 3–10 in the DSEIS show the locations of the sites, and Table 3–8 provides corner coordinates.

A. Eastern Long Island Sound Disposal Site

The ELDS alternative is located to the south of the mouth of Thames River estuary, approximately halfway between Connecticut and New York. The ELDS encompasses approximately the western half of the existing New London Disposal Site (NLDS), along with Sites NL-Wa and NL-Wb, which are adjacent areas immediately to the west of the NLDS (*see* DSEIS, Figure 3–9). The dimensions of the ELDS, which combines these three areas, are 1 × 2 nautical miles (nmi), for a total size of 2 square nautical miles (nmi^2). The closest upland points to the ELDS are Goshen Point, Connecticut, approximately 1.2 nmi (2.2 km) to the north, and Fishers Island, New York, approximately 1.4 nmi (2.6 km) to the southeast. The following are descriptions of the three areas that together would comprise the ELDS.

1. New London Disposal Site

The NLDS is located in the eastern part of the eastern Long Island Sound region and has been used for dredged material disposal since 1955 (SAIC, 2001b). This active open-water dredged material disposal site was previously selected by the USACE using their site selection authority under MPRSA 103(b), 33 U.S.C. 1413(b). The statute limits the use of USACE-selected sites to two five-year periods, 33 U.S.C. 1413(b), but Congress extended the period of use of the NLDS by five additional years by Public Law on December 23, 2011 (Pub. L. 112–74, Title I, Sec 116).

The center of the NLDS is located 3.1 nmi (5.4 km) south of Eastern Point in Groton, Connecticut. The site has an area of 1 nmi^2 (3.4 km^2) centered at 41°16.306′ N., 72°04.571′ W. (NAD83); corner coordinates are presented in Table 3–8. Water depths in the site range from approximately 46 to 79 feet (14 to 24 m). Most of the site is located within Connecticut waters, while a small portion in the southeastern corner of the site is located in New York state waters. However, this rule proposes to include only the western half of the NLDS, which would exclude the portion of the site that is in New York waters.

Approximately 5.4 mcy (4.1 million m^3) were disposed at the NLDS between 1955 and 1976. A total of approximately 3.5 mcy (2.6 million m^3) of dredged material have been placed at this location since it was formally selected in 1982. The dredged materials mounds on the seafloor result in an uneven seafloor within the site; the dredged material deposits can rise as much as 16 to 20 feet (5 to 6 m) above the surrounding seafloor.

The USGS mapped the sediment at the NLDS as predominantly sand, while sediments in the northernmost part of the site were mapped as gravelly. NUSC (1979) described the sediment at the site as generally fine sand. Much of the surface sediment at the site consists of placed dredged material. Sediment sampled by the DAMOS program at locations approximately 0.5 nmi (1 km) to the east and west of the NLDS consisted of silt/clay and very fine silty sand, which may reflect pre-disposal sediment textures at the NLDS.

2. Site NL-Wa

Site NL-Wa is immediately to the west of the NLDS and also has an area of 1 nmi^2 (3.4 km^2). Water depths range from approximately 45 feet (14 m) in the north, to 100 feet (30 m) in the south. The site consists of mostly sandy areas, but also an area of boulders and rocks in the northern part of the site (WHG, 2014). This boulder area may be a lag deposit of a glacial moraine. The water depth in parts of the boulder area is shallower than 59 feet (18 m).

3. Site NL-Wb

Site NL-Wb is immediately to the west of Site NL-Wa and has an area of 0.5 nmi^2 (1.7 km^2). Water depths across the site range from approximately 59 feet (18 m) in the north, to 95 feet (28 m) in the south. The site consists of an extension of the sandy areas of Site NL-Wa. The southwestern corner of Site NL-Wb contains an area of bedrock and boulders; this area is an extension of a larger area with a similar substrate further to the south. The bedrock appears as parallel ridges of dipping, layered rock that can be correlated to bedrock on shore. The bedrock area within Site NL-Wb also contains some sand waves. Bartlett Reef is located approximately 0.5 nmi (0.9 km) to the west of the western boundary of the site.

B. Niantic Bay Disposal Site

The NBDS alternative is located to the south of Niantic Bay, between the Connecticut and Thames Rivers (DSEIS, Figure 3–9). It consists of the historic NBDS and Site NB–E immediately to the east. The NBDS alternative includes areas that were used historically for dredged material disposal, but it has not been used since at least 1972.

The northern edge of the alternative site is located approximately 0.6 nmi (1.1 km) from Black Point (southwestern corner of Niantic Bay) and 1.6 nmi (3.0 km) from the Millstone Nuclear Power Station (southeastern corner of Niantic Bay). The Niantic Bay alternative has an area of 2.8 nmi^2, with a length of 2.08 nmi and a width of 1.33 nmi. Water depths at the site range from approximately 60 to 130 feet (18 to 40 m). The site is located entirely within Connecticut waters.

1. Niantic Bay Disposal Site (Historic)

The NBDS was used historically for the disposal of dredged materials between 1969 and 1972, when a total of 176,000 cy (135,000 m^3) of dredged material was disposed at this location. The site, however, has not been used for many years and it is not currently an active disposal site. Sediments at the site mostly consist of sand to the north and northwest and gravelly sediment with patches of gravel in the remainder of the area. There is a boulder area in the north-central part of the site and scour depressions in the south. The southeastern corner of the site abuts a bedrock area. The historic NBDS has an area of approximately 1.8 nmi^2 (6.2 km^2).

2. Site NB–E

Water depths at Site NB–E range from 43 feet (13 m) in the north to 230 feet (70 m) in the southeast. Surface sediments at the site are generally similar to sediments at the NBDS. The southwestern corner of Site NB–E contains a bedrock area, which is an extension of an exposed area of dipping bedrock layers to the south of the site. Site NB–E has an area of 1.0 nmi^2 (3.4 km^2). Bartlett Reef, a bedrock shoal, is located approximately 0.5 nmi (1 km) to the east of the site.

C. Cornfield Shoals Disposal Site

The CSDS alternative consists entirely of the active CSDS, which is located in the westernmost part of eastern Long Island Sound, approximately halfway between the states of Connecticut and New York (Figure 3–10). Like the NLDS, the CSDS was selected by the USACE using its site selection authority, and use of the site was then further extended by Congress on December 23, 2011 (Pub. L.–112–74, Title I, Sec 116). An estimated 1.2 mcy (0.95 million m^3) were disposed at the site between 1960 and 1976, and an additional 1.7 mcy (1.3 million m^3) between 1982 and 2013.

The center of the site is located 3.3 nmi (6.1 km) south of Cornfield Point in Old Saybrook, Connecticut. The site has an area of 1 nmi^2 (3.4 km^2) centered at 41°12.6858′ N., 72°21.4914′ W., (NAD83). The water depth is around 150 feet (50 m). The site is located mostly within Connecticut waters, with only approximately 17 percent in New York state waters.

Bottom currents generally move in an ENE–WSW direction. The seafloor around the CSDS is relatively flat, with longitudinal ripples and other bedforms that suggests that this area is sediment-starved. The site is classified as erosional/non-depositional in the DSEIS. The surface of the seafloor at the CSDS consists predominantly of gravel and gravelly sediment. Gravelly sediment consists of a mixture of 50 to 90% sand, silt and clay, with the remaining fraction consisting of gravel.

V. Compliance With Statutory and Regulatory Authorities

In proposing to designate a dredged material disposal site for the eastern portion of Long Island Sound, EPA has conducted the dredged material disposal site designation process consistent with the requirements of the MPRSA, NEPA, CZMA, the Endangered Species Act (ESA), the Magnuson-Stevens Fishery Conservation and Management Act (MSFCMA), and any other applicable legal requirements.

A. Marine Protection, Research, and Sanctuaries Act

Section 102(c) of the MPRSA, as amended, 33 U.S.C. 1412(c) *et seq.*, gives the Administrator of EPA authority to designate sites where ocean disposal of dredged material may be permitted. *See* also 33 U.S.C. 1413(b) and 40 CFR 228.4(e). The statute places no specific time limit on the term for use of an EPA-designated disposal site. Thus, EPA site designations can be for an indefinite term and are generally thought of as long-term designations. EPA may, however, place various restrictions or limits on the use of a site based on the site's capacity to accommodate dredged material or other environmental concerns. *See* 33 U.S.C. 1412(c).

Section 103(b) of the MPRSA, 33 U.S.C. 1413(b), provides that any ocean disposal of dredged material should occur at EPA-designated sites to the maximum extent feasible. In the absence of an available EPA-designated site, however, the USACE is authorized to "select" appropriate disposal sites. In 1992, Congress amended MPRSA section 103(b) to place maximum time limits on the use of USACE-selected disposal sites. Specifically, the statute restricted the use of such sites to two separate five-year terms. There are no EPA-designated dredged material disposal sites in the eastern portion of Long Island Sound and past open-water disposal of dredged material from projects subject to MPRSA requirements under section 106(f) has been conducted in this area of Long Island Sound at sites used pursuant to the USACE site selection authority. The two active USACE-selected sites, the NLDS and CSDS, will no longer be available after December 23, 2016, however, when their Congressionally-authorized term of use expires.

The Ocean Dumping Regulations, *see generally* 40 CFR Subchapter H, prescribe general and specific criteria at 40 CFR 228.5 and 228.6, respectively, to guide EPA's choice of disposal sites for final designation. EPA regulations at 40 CFR 228.4(e)(1) provide, among other things, that EPA will designate any disposal sites by promulgation in 40 CFR part 228. Ocean dumping sites designated on a final basis are promulgated at 40 CFR 228.15. Section 102(c) of the MPRSA, 33 U.S.C. 1412(c), and 40 CFR 228.3 also establish requirements for EPA's ongoing management and monitoring, in conjunction with the USACE, of disposal sites designated by EPA to ensure that unacceptable, adverse environmental impacts do not occur. Examples of such management and monitoring include the following: Regulating the times, rates, and methods of disposal, as well as the quantities and types of material that may be disposed; conducting pre- and post-disposal monitoring of sites; conducting disposal site evaluation and designation studies; and, if warranted, recommending modification of site use and/or designation conditions and restrictions. *See* also 40 CFR 228.7, 228.8, 228.9.

Finally, a disposal site designation by EPA does not actually authorize any dredged material to be disposed of at that site. It only makes that site available as a possible management option if various other conditions are met first. Use of the site for dredged material disposal must be authorized by the Corps under MPRSA section 103(b), subject to EPA review, and such disposal at the site can only be authorized if: (1) It is determined that there is a need for open-water disposal for that project (*i.e.*, that there are no practicable alternatives to such disposal that would cause less harm to the environment); and (2) the dredged material satisfies the applicable environmental impact criteria specified in EPA's regulations at 40 CFR part 227. *See* 40 CFR 227.1(b), 227.2 and 227.16. Furthermore, the authorization for disposal is also subject to review for compliance with other applicable legal requirements, which may include the ESA, the MSFCMA, the CWA (including any applicable state water quality standards), NEPA, and the CZMA. The following describes EPA's evaluation of the ELDS, NBDS, and CSDS alternatives pursuant to the applicable site evaluation criteria, and its compliance with site management and monitoring requirements.

EPA undertook its evaluation of whether to designate any dredged material disposal sites in the eastern Long Island Sound region pursuant to its authority under MPRSA section 102(c) in response to several factors. These factors include the following:

- The determination by EPA, based on the evaluation of projected dredging needs over the 30-year planning horizon and alternatives to open-water disposal conducted for the USACE's DMMP, that the potential alternatives to open-water disposal do not provide sufficient capacity to accept the quantity of dredged material expected to be generated over the next 30 years in the region;
- The prohibition on use of the NLDS and CSDS disposal sites after December 23, 2016, pursuant to the USACE site selection authority under MPRSA section 103(b) and the five-year extension provided by Congress under Public Law 112–74, Title I, Sec 116.
- The understanding that in the absence of an EPA-designated disposal site or sites, any necessary open-water disposal would either be stymied, despite the importance of dredging for ensuring navigational safety and facilitating marine commercial and recreational activities, or the USACE would have to undertake additional short-term site selections, perhaps many of them, in the future;
- The clear Congressional preference expressed in MPRSA section 103(b) that any open-water disposal of dredged material take place at EPA-designated sites, if feasible;
- The fact that the two closest EPA-designated sites outside the eastern Long Island Sound region, the CLDS and RISDS, do not have the capacity to accept the quantity of suitable dredged material estimated to be generated from the eastern region of Long Island Sound, which was not anticipated when these sites were designated in 2005, and the additional fact that the two sites are 29.9 nmi and 51.4 nmi respectively from the Connecticut River dredging center, which would significantly increase transportation costs and project durations, while also increasing energy use, air emissions, and the risk of spills or short-dumps; and
- EPA's policy view that it is generally environmentally preferable to concentrate any open-water disposal at sites that have been used historically and at fewer sites, rather than relying on the selection of multiple sites to be used for a limited time, *see* 40 CFR 228.5(e).

EPA's evaluation considered whether there was a need to designate one or more disposal sites for long-term dredged material disposal, including an assessment of whether other dredged material management methods could reasonably be judged to obviate the need for such designations. Having concluded that there was a need for open-water disposal sites, EPA then assessed whether there were sites that would satisfy the applicable environmental criteria to support a site designation under MPRSA section 102(c). The MPRSA and EPA regulations promulgated thereunder impose a number of requirements related to the designation of dredged material disposal sites. These include procedural requirements, specification of criteria for use in site evaluations, and the requirement that a SMMP must be developed for all designated sites. As discussed below, EPA complied with each of these requirements in proposing to designate the ELDS.

1. Procedural Requirements

MPRSA sections 102(c) and 103(b) indicate that EPA may designate ocean disposal sites for dredged material. EPA regulations at 40 CFR 228.4(e) specify that dredged material disposal sites will be "designated by EPA promulgation in this [40 CFR] part 228 . . . ." EPA regulations at 40 CFR 228.6(b) direct that if an EIS is prepared by EPA to assess the proposed designation of one or more disposal sites, it should include the results of an environmental evaluation of the proposed disposal site(s), the Draft EIS (DEIS) should be presented to the public along with a proposed rule for the proposed disposal site designation(s), and that a Final EIS (FEIS) should be provided at the time of final rulemaking for the site designation. EPA has complied with all procedural requirements related to the publication of this proposed rule and associated DSEIS. The Agency has prepared a thorough environmental evaluation of the recommended alternative site being proposed for designation, the other two alternative sites still being considered, and other courses of action (including the option of not designating open-water disposal sites). This evaluation is presented in the DSEIS (and related documents) and this proposed rule.

2. Disposal Site Selection Criteria

EPA regulations under the MPRSA identify four general criteria and 11 specific criteria for evaluating locations for the potential designation of dredged material disposal sites. *See* 40 CFR 228.4(e), 228.5 and 228.6. The evaluation of the ELDS with respect to the four general and 11 specific criteria is discussed in detail in the DSEIS and supporting documents and is summarized below. The evaluation of the NBDS and CSDS with respect to the criteria also is discussed in detail in the DSEIS and supporting documents, but is not discussed in detail below because EPA is not currently proposing to designate these sites.

General Criteria (40 CFR 228.5)

As described in the DSEIS, and summarized below, EPA has determined that the ELDS, NBDS, and CSDS satisfy the four general criteria specified in 40 CFR 228.5. This is discussed in Chapter 5 and summarized in Table 5–9, "Summary of Impacts for Action and No Action Alternatives," of the DSEIS.

i. Sites must be selected to minimize interference with other activities in the marine environment, particularly avoiding areas of existing fisheries or shellfisheries, and regions of heavy commercial or recreational navigation (40 CFR 228.5(a)).

EPA's evaluation determined that use of the ELDS would cause minimal interference with the aquatic activities identified in the criterion. The site is not located in shipping lanes or any other region of heavy commercial or recreational navigation. In addition, the site is not located in an area that is important for commercial or recreational fishing or shellfish harvesting. EPA used Geographic Information System (GIS) software to overlay the locations of various uses and natural resources of the marine environment on the disposal site location and surrounding areas (including their bathymetry). Analysis of this data indicated that use of the site would have minimal potential for interfering with other existing or ongoing uses of the marine environment in and around the ELDS, including lobster harvesting or fishing activities. In addition, the western half of the ELDS has been used for dredged material disposal for many years (as the NLDS) and not only has this activity not significantly interfered with the uses identified in the criterion, but mariners in the area are accustomed to use of this site. Finally, time-of-year restrictions (also known as "environmental windows") imposed to protect fishery resources will typically limit dredged material disposal activities to the months of October through April, thus further minimizing any possibility of interference with the various activities specified in the criterion. The NBDS and CSDS also meet this criterion for largely the same reasons.

ii. Sites must be situated such that temporary perturbations to water quality or other environmental conditions during initial mixing caused by disposal operations would be reduced to normal ambient levels or to undetectable contaminant concentrations or effects before reaching any beach, shoreline, marine sanctuary, or known geographically limited fishery or shellfishery (40 CFR 228.5(b)).

EPA's analysis concludes that the ELDS satisfies this criterion. First, the site is a significant distance from any beach, shoreline, marine sanctuary (in fact, there are no federally-designated marine sanctuaries in Long Island Sound), or known geographically limited fishery or shellfishery. Second, the site will be used only for the disposal of dredged material determined to be suitable for open-water disposal by application of the MPRSA's ocean dumping criteria. *See* 40 CFR part 227. These criteria include provisions related to water quality and account for initial mixing. *See* 40 CFR 227.4, 227.5(d), 227.6(b) and (c), 227.13(c), 227.27, and 227.29. Data evaluated during development of the DSEIS, including data from monitoring conducted during and after past disposal activities, indicates that any temporary perturbations in water quality or other environmental conditions at the site during initial mixing from disposal operations will be limited to the immediate area of the site and will neither cause any significant environmental degradation at the site nor reach any beach, shoreline, marine sanctuary, or other important natural resource area. The NBDS and CSDS also meet this criterion for the same reasons.

iii. The sizes of disposal sites will be limited in order to localize for identification and control any immediate adverse impacts, and to permit the implementation of effective monitoring and surveillance to prevent adverse long-range impacts. Size, configuration, and location are to be determined as part of the disposal site evaluation (40 CFR 228.5(d)).

EPA has determined, based on the information presented in the DSEIS, that the ELDS, NBDS, and CSDS alternatives are sufficiently limited in size to allow for the identification and control of any immediate adverse impacts, and to permit the implementation of effective monitoring and surveillance to prevent adverse long-range impacts. The maximum combined size of the three sites is approximately 5.8 nmi2, which is just 0.015 (1.5 percent) of the approximately 370 nmi^2 surface area of the eastern Long Island Sound region (the ZSF excluding Block Island Sound), and just 0.0043 (less than one-percent) of the surface area of the entire Long Island Sound. The long history of dredged material disposal site monitoring in New England through the

DAMOS program, and specifically at active and historic dredged material disposal sites in Long Island Sound, provides ample evidence that these surveillance and monitoring programs are effective at determining physical, chemical, and biological impacts at sites of the size of the options considered in this case.

All three alternative sites are identified by specific coordinates spelled out in the DSEIS, and the use of precision navigation equipment in both dredged material disposal operations and monitoring efforts will enable accurate disposal operations and contribute to effective management and monitoring of the sites. Detailed plans for the management and monitoring of the ELDS are described in the SMMP (Appendix I of the DSEIS). Finally, as discussed herein and in the DEIS, EPA has tailored the boundaries of each of the alternative sites in light of site characteristics, such as local currents and bottom features, so that the area and boundaries of the sites are optimized for environmentally sound dredged material disposal operations.

iv. EPA will, wherever feasible, designate ocean dumping sites beyond the edge of the continental shelf and other such sites that have been historically used (40 CFR 228.5(e)).

EPA evaluated sites beyond the edge of the continental shelf and historical disposal sites in Long Island Sound as part of the alternatives analysis conducted for the DSEIS. The continental shelf extends about 60 nmi seaward from Montauk Point, New York, and a site located on the continental slope would result in a transit of approximately 80 nmi from New London. This evaluation determined that the long distances and travel times between the dredging locations in eastern Long Island Sound and the continental shelf posed significant environmental, operational, safety, and financial concerns, rendering such options unreasonable. Environmental concerns include increased risk of encountering endangered species during transit, increased fuel consumption and air emissions, and greater potential for accidents in transit that could lead to dredged material being dumped in unintended areas.

As described in the Disposal Site Descriptions section, the ELDS, NBDS, and CSDS all encompass the footprints of historically used sites. To the extent that the site boundaries have been adjusted to include adjacent areas outside of the existing sites, EPA has concluded that these adjustments will be environmentally beneficial, as discussed in the DSEIS. For example, rather than propose designation of the existing NLDS, the eastern half of which is at capacity and nearing depths that could lead to scouring of the sediment by surface currents and storms, EPA is proposing a new ELDS that encompasses the western half of the existing NLDS along with two adjacent areas immediately to the west of the NLDS. These two adjacent areas have been determined to be containment areas by physical oceanographic modeling. Long-term monitoring of the three alternative sites, or at least the historically used parts of them, has shown minimal adverse impacts to the adjacent marine environment and rapid recovery of the benthic community in the disposal mounds. While there are also other historically used disposal sites in eastern Long Island Sound, the analysis in the DSEIS concludes that the ELDS, NBDS, and CSDS are the preferable locations. Thus, designation of the ELSD, NBDS, and/or CSDS would be consistent with this criterion.

a. Specific Criteria (40 CFR 228.6)

In addition to the four general criteria discussed above, 40 CFR 228.6(a) lists eleven specific factors to be used in evaluating the impact of using the site(s) for dredged material disposal under the MPRSA. Compliance with the eleven specific criteria is discussed below. It is also discussed in detail in Chapter 5 and summarized in Table 5–13, "Summary of Impacts at the Alternative Sites," of the DSEIS.

i. Geographical Position, Depth of Water, Bottom Topography and Distance From Coast (40 CFR 228.6(a)(1)).

Based on analyses in the DSEIS, EPA has concluded that the geographical position (*i.e.*, location), water depth, bottom topography (*i.e.*, bathymetry), and distance from coastlines of the ELDS (and part of the NBDS) will facilitate containment of dredged material within site boundaries, and reduce the likelihood of material being transported away from the site to adjacent sea floor areas. As described in the preceding Disposal Sites Description section and in the above discussion of compliance with general criteria iii and iv (40 CFR 228.5(c) and (d)), all three sites (ELDS, NBDS and CSDS) are located far enough from shore and are in deep enough water to avoid adverse impacts to the coastline.

The ELDS and northeastern portion of the NBDS are containment areas, so disposal of dredged material there is expected to stay in those sites and not cause adverse effects to the adjacent seafloor areas. The CSDS and remaining portions of the NBDS are dispersive, so any dredged material disposed there would not be expected to stay within the site boundaries. However, disposal site monitoring, ambient water quality monitoring, and fisheries surveys have not documented any adverse impacts from the use of the CSDS since the early 1980s. The closest points of land to the ELDS are Goshen Point, Connecticut, approximately 1.2 nmi (2.2 km) to the north, and Fishers Island, New York, approximately 2 nmi (3.2 km) to the southeast, in water depths ranging from approximately 45 feet (14 m) in the north to 100 feet (30 m) in the south. The northern edge of the NBDS alternative is located approximately 0.6 nmi (1.1 km) from Black Point (southwestern corner of Niantic Bay) and 1.6 nmi (3.0 km) from the Millstone Nuclear Power Station (southeastern corner of Niantic Bay). Water depths at the site range from approximately 60 to 130 feet (18 to 40 m). The center of the CSDS is 3.3 nmi (6.1 km) south of Cornfield Point in Old Saybrook, Connecticut, and the water depth at the site is around 150 feet (50 m).

As discussed in the DSEIS, long-term monitoring of disposal sites in Long Island Sound has indicated that creating mounds above a depth of 46 feet (14 meters) can result in material being removed from the mounds by currents. All three sites are of a sufficient depth to allow the disposal of the amount of material that is projected over the 30-year planning horizon without exceeding this depth threshold. As discussed in the DSEIS, the entire ELDS and the northeastern part of the NBDS are containment areas and, as a result, EPA expects material placed at these sites to remain there. As a result, any short-term impacts from dredged material placement will be localized and this, together with other regulatory requirements described elsewhere in this document, will facilitate prevention of any adverse impacts at the sites.

The CSDS alternative and a part of the NBDS, however, are dispersive areas from which dredged material disposed there would likely be eroded over time. This material would then be dispersed in the water column and transported predominantly toward the west. As a result, past disposal at the CSDS has been limited to certain types of sediments (*i.e.*, sandy material). If the NBDS were designated, similar restrictions would likely be appropriate regarding any use of the dispersive areas of the site. Monitoring of the CSDS has determined that past and present management practices have been successful in minimizing short-term, long-term, and cumulative impacts to water quality and benthic habitat from dredged material disposal. EPA expects that similar results would follow from using the dispersive portions of the NBDS with similar restrictions.

ii. Location in Relation To Breeding, Spawning, Nursery, Feeding, or Passage Areas of Living Resources in Adult or Juvenile Phases (40 CFR 228.6(a)(2)).

EPA considered the proposed ELDS and the other two sites in relation to breeding, spawning, nursery, feeding, and passage areas for adult and juvenile phases (*i.e.,* life stages) of living resources in Long Island Sound. From this analysis, EPA concluded that, while disposal of suitable dredged material at the ELDS, NBDS, or CSDS would cause some short-term, localized effects, overall it would not cause adverse effects to the habitat functions and living resources specified in the above criterion. As previously noted, the maximum combined size of the three sites is approximately 5.8 nmi^2, which is just 0.015 (1.5 percent) of the approximately 370 nmi^2 surface area of the eastern Long Island Sound region (the ZSF excluding Block Island Sound), and just 0.0043 (less than one-percent) of the surface area of the entire Long Island Sound.

Generally, there are three primary ways that dredged material disposal could potentially adversely affect marine resources. First, disposal can cause physical impacts by injuring or burying less mobile fish, shellfish, and benthic organisms, as well as their eggs and larvae. Second, tug and barge traffic transporting the dredged material to a disposal site could possibly collide or otherwise interfere with marine mammals and reptiles. Third, contaminants in the dredged material could potentially bioaccumulate through the food chain. However, EPA and the other federal and state agencies that regulate dredging and dredged material disposal impose requirements that prevent or greatly limit the potential for these types of impacts to occur.

For example, the agencies impose "environmental windows," or time-of-year restrictions, for both dredging and dredged material disposal. This type of restriction has been a standard practice for more than a decade in Long Island Sound, and New England generally, and is incorporated in USACE permits and authorizations in response to consultation with federal and state natural resource agencies (*e.g.,* NMFS). Dredged material disposal in Long Island Sound is generally limited to the period between October 1 and April 30 to avoid time periods when any threat of effects on aquatic organisms would be greater. Indeed, environmental windows are often set depending on the location of specific dredging projects in relation to certain fish and shellfish species. For example, dredging in nearshore areas where winter flounder spawning occurs is generally prohibited between February 1 and April 1; dredging that may interfere with anadromous fish runs is generally prohibited between April 1 and May 15; and dredging that may adversely affect shellfish is prohibited between June 1 and September 30. These environmental windows, in effect, serve to further restrict periods during which dredged material disposal would occur.

Another benefit of using environmental windows is that they reduce the likelihood of dredged material disposal activities interfering with marine mammals and reptiles. While there are several species of marine mammal or reptile, such as harbor porpoises, long-finned pilot whales, seals, and sea turtles, that either inhabit or migrate through Long Island Sound, most of them either leave the Sound during the winter months for warmer waters to the south or are less active and remain near the shore. There also are many species of fish (*e.g.,* striped bass, bluefish, scup) and invertebrates (*e.g.,* squid) that leave the Sound during the winter for either deeper water or warmer waters to the south, thus avoiding the time of year when most dredging and dredged material disposal occurs. The use of environmental windows has been refined over time and is considered an effective management tool to minimize impacts to marine resources.

Dredged material disposal will, however, have some localized impacts to fish, shellfish, and benthic organisms, such as clams and worms, that are present at a disposal site (or in the water column directly above the site) during a disposal event. The sediment plume may entrain and smother some fish in the water column, and may bury some fish, shellfish, and other marine organisms on the sea floor. It also may result in a short-term loss of forage habitat in the immediate disposal area, but the DAMOS program has documented the recolonization of disposal mounds by benthic infauna within 1–3 years after disposal and this pattern would be expected at the sites evaluated in the DSEIS. As discussed in the DSEIS (section 5.2.2), over time, disposal mounds recover and develop abundant and diverse biological communities that are healthy and able to support species typically found in the ambient surroundings. Some organisms may burrow deeply into sediments, often up to 20 inches, and are more likely to survive a burial event.

To further reduce potential environmental impacts associated with dredged material disposal, the dredged material from each proposed dredging project will be subjected to the MPRSA sediment testing requirements set forth at 40 CFR part 227 to determine its suitability for open-water disposal. Suitability for open-water disposal is determined by testing the proposed dredged material for toxicity and bioaccumulation and by quantifying the risk to human health from consuming marine organisms that are exposed to dredged material and its associated contaminants using a risk assessment model. If it is determined that the sediment is unsuitable for open-water disposal—that is, that it may unreasonably degrade or endanger human health or the marine environment—it cannot be disposed at disposal sites designated under the MPRSA. *See* 40 CFR 227.6. Therefore, EPA does not anticipate significant effects on marine organisms from dredged material disposal at the sites under evaluation.

EPA also is complying with the ESA by consulting with the NMFS and U.S. Fish and Wildlife Service (USFWS) concerning EPA's conclusion that the designation of the ELDS, NBDS, or CSDS would not likely adversely affect federally listed species under their respective jurisdictions or any habitat designated as critical for such species. Additionally, EPA consulted with NMFS under the MSFCMA on potential impacts to essential fish habitat (EFH). NMFS determined that the use of environmental windows and the stringent testing requirements were sufficient steps to minimize any impacts to EFH and did not offer additional conservation recommendations. Further details on these consultations are provided in the DSEIS and the section below describing compliance with the ESA and MSFCMA.

EPA recognizes that dredged material disposal causes some short-term, localized adverse effects to marine organisms in the immediate vicinity of each disposal event. But because dredged material disposal would be limited to suitable material at the 1–3 small sites under consideration here (see above regarding compliance with general criteria (40 CFR 2285(e)), and during only several months of the year, EPA concludes that designating ELDS, NBDS, or CSDS would not cause unacceptable or unreasonable adverse impacts to breeding, spawning, nursery, feeding, or passage areas of living resources in adult or juvenile phases.

There is no evidence of long-term effects on benthic processes or habitat conditions.

iii. Location in Relation to Beaches and Other Amenity Areas (40 CFR 228.6(a)(3)).

EPA's analysis concludes that the ELDS, NBDS, and CSDS all satisfy this criterion. All three sites are far enough away from beaches, parks, wildlife refuges, and other areas of special concern to prevent adverse impacts to these amenities and, as previously noted, there are no marine sanctuaries in Long Island Sound. As previously described, the ELDS, NBDS, and CSDS are 1.2 nmi (2.2 km), 0.6 nmi (1.1 km), and 2.8 nmi (5.2 km) from the nearest shore, respectively, and none of the sites is closer than 1.7 nmi (3.2 km) to public beaches in either Connecticut or New York. Based on modeling results that are presented in section 5.5.3 of the DSEIS, and past monitoring of actual disposal activities, this distance is beyond any expected transport of dredged material due to tidal motion or currents. As noted above, any temporary perturbations in water quality or other environmental conditions at the sites during initial mixing from disposal operations will be limited to the immediate area of the sites and will not reach any beach, parks, wildlife refuges, or other areas of special concern.

Thus, EPA does not anticipate that the use of the ELDS, NBDS, or CSDS would cause any adverse impacts to beaches or other amenity areas.

iv. Types and Quantities of Wastes Proposed To Be Disposed of, and Proposed Methods of Release, Including Methods of Packing the Waste, if Any (40 CFR 228.6(a)(4)).

The typical composition of dredged material to be disposed at the sites is expected to range from predominantly "clay-silt" to "mostly sand." This expectation is based on data from historical dredging projects from the eastern region of Long Island Sound. For federal dredging projects and private projects generating more 25,000 cubic yards of dredged material, EPA and the USACE will conduct sediment suitability determinations applying the criteria for testing and evaluating dredged material under 40 CFR 227 and further guidance in the "Regional Implementation Manual for the Evaluation of Dredged Material Proposed for Disposal in New England Waters" (EPA, 2004), and the material would have to satisfy these suitability criteria before it could be authorized for disposal under the MPRSA. Private dredging projects generating up to 25,000 cubic yards will continue to be regulated under CWA section 404. The requirements under the MPRSA and the CWA are discussed in detail in the DSEIS.

The ELDS, NBDS, and CSDS would receive dredged material that is transported by either government or private contractor hopper dredges or oceangoing bottom-dump barges ("scows") towed by tugboat. Both types of equipment release the material at or very near the surface, which is the standard operating procedure for this activity. The disposal of this material will occur at specific coordinates marked by buoys and will be placed so as to concentrate material from each disposal project. This concentrated placement is expected to help minimize bottom impacts to benthic organisms. In addition, there are no plans to pack or package dredged material prior to disposal.

Furthermore, it should be emphasized that the three alternative sites are only being considered for the disposal of dredged material; disposal of other types of material will not be allowed at these sites. It also should be noted that the disposal of certain other types of material is expressly prohibited by the MPRSA and EPA regulations (*e.g.,* industrial waste, sewage sludge, chemical warfare agents, insufficiently characterized materials) (33 U.S.C. 1414b; 40 CFR 227.5).

As previously discussed, dredging in eastern Long Island Sound is projected to generate approximately 22.6 million cubic yards (mcy) of dredged material over the next 30 years, including 17.9 mcy from Connecticut ports and harbors and 4.7 mcy from ports and harbors in New York. Of the total amount of 22.6 mcy, approximately 13.5 mcy are projected to be fine-grained sediment that meets MPRSA and CWA standards for aquatic disposal (*i.e.,* "suitable" material), and 9.1 mcy are projected to be course-grained sand that also meets MPRSA and CWA standards for aquatic disposal (*i.e.,* also "suitable" material). Even if none of the sand is used beneficially, which is highly unlikely given the high demand for this resource, the maximum quantity of dredged material that may possibly be disposed of at one or more of the three alternatives is approximately 22.6 mcy, and EPA expects that increased efforts to develop and use practicable alternatives to open-water disposal will reduce that amount significantly. Since the estimated capacity of the ELDS, NBDS, and CSDS is 27 mcy, 27 mcy, and unlimited respectively, there is more than sufficient capacity even if only ELDS or one of the other two alternatives is designated for long-term use. (As previously stated, EPA is not considering designating the CSDS alone because it is a dispersive site.) For all of these reasons, no significant adverse impacts are expected to be associated with the types and quantities of dredged material that may be disposed at the sites.

v. Feasibility of Surveillance and Monitoring (40 CFR 228.6(a)(5)).

Monitoring and surveillance are expected to be feasible at all three sites, although the ELDS and the northeast portion of the NBDS would be most conducive to monitoring because they're containment sites and material disposed there is expected to stay there. The ELDS, NBDS, and CSDS are all readily accessible for bathymetric and side-scan sonar surveys and the NLDS portion of the ELDS and the CSDS have been successfully monitored by the USACE over the past 35 years under the DAMOS program. Upon designation of a site or sites, monitoring would continue under the DAMOS program in accordance with the most current approved Site Management and Monitoring Plan (SMMP) for each site. A draft SMMP has been developed only for the ELDS at this time, since it is EPA's preferred alternative, but EPA will develop SMMPs for any other sites that may be designated following a similar format. As a containment site, the ELDS is conducive to the type of monitoring most commonly conducted at dredged material disposal sites, including side-scan sonar, sediment profile imaging, and sediment grab sampling. The draft SMMP for the ELDS is included as Appendix I of the DSEIS.

While the CSDS and transitional part of the NBDS can be monitored, they are more dispersive sites, which means that currents take dredged sediments away from the sites over time. Therefore, it is not possible to accurately track the fate of material placed at these sites. As explained above, that is why use of the CSDS has been limited over the years to receiving sediments from non-industrial harbors and channels, like the mouth of the Connecticut River. EPA is not currently proposing to designate the NBDS or CSDS, but if that changes after consideration of public comments, EPA would prepare an SMMP for public review and comment in conjunction with a proposal to designate the site. The SMMPs are subject to review and updating at least once every ten years, if necessary, and may be subject to additional revisions based on the results of site monitoring and other new information. Any such revisions will be closely coordinated with other federal and state resource management agencies and stakeholders during the review and approval process and will become final only when approved by EPA, in conjunction with the USACE. *See* 33 U.S.C. 1413 (c)(3).

vi. Dispersal, Horizontal Transport and Vertical Mixing Characteristics of the Area, Including Prevailing Current Direction and Velocity, if Any (40 CFR 228.6(a)(6)).

Although the interactions of bathymetry, wind-generated waves, and river and ocean currents in Long Island Sound are complex, the ELDS, NBDS, and CSDS are located in areas that are generally calm except during storms. (Dredging and dredged material disposal would not be conducted during storm events. See *e.g.,* 40 CFR 228.15(b)(4)(vi)(L)). Consistent with this, past monitoring during disposal operations at the NLDS (in the vicinity of the proposed ELDS), NBDS, and CSDS revealed minimal drift of sediment out of the disposal site area as it passed through the water column.

Conditions are more complicated at the seafloor within the alternative disposal sites. Disposal site monitoring has confirmed that peak wave-induced bottom current velocities are not sufficient to cause significant erosion of dredged material placed at either the ELDS or the containment portions of the NBDS. As noted above, physical oceanographic monitoring and modeling has indicated that the ELDS and portions of the NBDS are depositional locations that collect, rather than disperse, sediment. For these reasons, EPA has determined that the dispersal, horizontal transport, and vertical mixing characteristics, as well as the current velocities and directions at the ELDS and within portions of the NBDS are appropriate to support their designation as dredged material disposal sites.

As discussed above, EPA also has determined that the CSDS and portions of the NBDS are dispersive sites with bottom currents that would likely move dredged material away from the site to surrounding areas. Therefore, EPA does not currently favor designating these sites, but they could be designated for limited use for the placement of suitable sediments with similar characteristics to native sediments in the general vicinity of the sites. This is how the CSDS was used in the past. EPA is interested in receiving comments concerning the option of designating the CSDS for such limited use.

vii. Existence and Effects of Current and Previous Discharges and Dumping in the Area (Including Cumulative Effects) (40 CFR 228.6(a)(7)).

As previously described in the Disposal Sites Descriptions section, the portion of the ELDS that was used historically as the NLDS has received approximately 8.9 mcy (6.7 million m^3) since 1955. The NBDS is not currently an active disposal site, but it was used between 1969 and 1972, when a total of 176,000 cy (135,000 m^3) of dredged material was disposed at this location. The CSDS has received an estimated 2.9 mcy of dredged material (2.25 million m^3) since 1960.

Until the passage of the CWA in 1972, dredged material disposal was not a heavily regulated activity. Since 1972, open-water disposal in Long Island Sound has been subject to the sediment testing and alternatives analysis provisions of section 404 of the CWA. With passage of the Ambro Amendment in 1980 (which was further amended in 1990), dredged material disposal from all federal projects and non-federal projects generating more than 25,000 cubic yards of material became subject to the requirements of both CWA section 404 and the MPRSA. The result of these increasingly stringent regulatory requirements for dredged material disposal, combined with the reduction in contaminants entering waterways from other Clean Water Act programs, is that there has been a steady, measurable improvement in the quality of material that has been allowed to be placed at the NLDS portion of the ELDS and CSDS over the past 35 years.

The NLDS portion of the ELDS and CSDS both have been used on a consistent basis since the early 1980s pursuant to the USACE's short-term site selection authority under section 103(b) of the MPRSA (33 U.S.C. 1413(b)). Since then, disposal operations at these sites have been carefully managed and the material disposed there has been monitored. In EPA's view, past use of these sites generally makes them preferable to more pristine sites that have either not been used or have been used in the more distant past. *See* 40 CFR 228.5(e). Continuing to use existing sites, as long as they have remaining capacity, rather using a multitude of sites, helps to limit or concentrate the footprint of dredged material disposal on the seafloor of Long Island Sound. While the effects of placing suitable dredged material at a disposal site are primarily limited to short-term physical effects, such as burying benthic organisms in the location where the material is placed, EPA regards it to be preferable to concentrate such effects in particular areas and leave other areas untouched as much as possible.

That said, EPA's evaluation of data and modeling results indicates that past disposal operations have not resulted in unacceptable or unreasonable environmental degradation, and that there should be no such adverse effects in the future from the projected use of any of the three sites, although it would be easier to determine this at the ELDS and the containment portion of the NBDS, since the material is expected to stay at those sites and could be monitored. As part of this conclusion, discussed in detail in the DSEIS, EPA found that there should be no significant adverse cumulative environmental effects from using these sites on a long-term basis for dredged material disposal in compliance with all applicable regulatory requirements regarding sediment quality and site usage.

viii. Interference With Shipping, Fishing, Recreation, Mineral Extraction, Desalination, Fish and Shellfish Culture, Areas of Special Scientific Importance and Other Legitimate Uses of the Ocean (40 CFR 228.6(a)(8)).

In evaluating whether disposal activity at the sites could interfere with shipping, fishing, recreation, mineral extraction, desalination, fish or shellfish culture, areas of scientific importance, and other legitimate uses of the ocean, EPA considered both the effects of placing dredged material on the bottom of the Sound at the ELDS, NBDS, and CSDS and any effects from vessel traffic associated with transporting the dredged material to the disposal sites. From this evaluation, EPA concluded there would be no unacceptable or unreasonable adverse effects on the considerations noted in this criterion. Some of the factors listed in this criterion have already been discussed above due to the overlap of this criterion with aspects of certain other criteria. Nevertheless, EPA will address each point below.

The ELDS is the only site in close proximity to significant shipping activity. The eastern boundary of the proposed ELDS is one-half mile west of the eastern boundary of the current NLDS; this shift to the west would move the disposal site out of about half of the Submarine Transit Corridor into New London Harbor, further reducing the potential for conflicts between the disposal site and submarine traffic. Vessel traffic generated by disposal activity is expected to be similar to that which has occurred over the past 20–30 years, which has not interfered with other shipping activity. Moreover, research by EPA and the USACE concluded that after disposal at any of the three sites, resulting water depths will be sufficient to permit navigation in the area without interference. (And by providing an open-water alternative for dredged material disposal in the absence of environmentally preferable, practicable alternatives, the sites are likely to improve and facilitate navigation in many of the harbors, bays, rivers and channels around eastern Long Island Sound.)

EPA also carefully evaluated the potential effects on commercial and recreational fishing for both finfish and shellfish (including lobster) of designating the ELDS, NBDS, and CSDS for dredged material disposal and concluded that there would be no unreasonable or unacceptable adverse effects. As discussed above in relation to other site evaluation criteria, dredged material disposal will only have short-term, incidental, and insignificant effects on organisms in the disposal sites and no appreciable effects beyond the sites. Indeed, since past dredged material disposal has been determined to have no significant adverse effects on fishing, the similar projected levels of future disposal activities at the designated sites also are not expected to have any significant adverse effects.

Four main reasons that EPA concluded that no unacceptable adverse effects would occur from placing dredged material at the site alternatives are discussed below. First, as discussed above, EPA has concluded that any contaminants in material permitted for disposal—having satisfied the dredged material criteria in the regulations that restrict any toxicity and bioaccumulation—will not cause any significant adverse effects on fish, shellfish, or other aquatic organisms. Because both the ELDS and portions of the NBDS are containment areas, dredged material disposed at those sites is expected to remain there. If the CSDS and/or dispersive portion of the NBDS were to be designated, EPA would restrict the types of material to be placed at those sites, as discussed above.

Second, as also discussed above, the disposal sites do not encompass any especially important, sensitive, or limited habitat for the Sound's fish and shellfish, such as key spawning or nursery habitat for species of finfish. Numerous studies and data reviewed by EPA and the USACE indicate that there is low potential for any future incremental risk from the placement of dredged sediments at the three alternative sites, either in the long- or short-term.

Third, while EPA found that a small number of demersal fish (*e.g.,* winter flounder), shellfish (*e.g.,* clams and lobsters), benthic organisms (*e.g.,* worms), and zooplankton and phytoplankton could be lost due to the physical effects of disposal (*e.g.,* burial of organisms on the bottom by dredged material and entrainment of plankton in the water column by dredged material upon its release from a disposal barge), EPA also determined that these minor, temporary adverse effects would be neither unreasonable nor unacceptable. This determination was based on EPA's conclusion that the numbers of organisms potentially affected represent only a minuscule percentage of those in eastern Long Island Sound, and on DAMOS monitoring that consistently documents the rapid recovery of the benthic community in an area that has received dredged material. In addition, any physical effects will be further limited by the relatively few months in which disposal activities could be permitted by the environmental window (or time-of-year) restrictions.

Fourth, EPA has determined that vessel traffic associated with dredged material disposal will not have any unreasonable or unacceptable adverse effects on fishing. As explained above, environmental window restrictions will limit any disposal to the period between October 1 and April 30, and often to fewer months depending on species-specific restrictions for each dredging project, each year. Moreover, there is generally far less vessel traffic in the months when disposal would occur due to the seasonal nature of recreational boating and commercial shipping. There currently are no mineral extraction activities or desalinization facilities in the eastern Long Island Sound region with which disposal activity could potentially interfere. Energy transmission pipelines and cables are located near the sites, but none are within their boundaries. No finfish aquaculture currently takes place in Long Island Sound and the only form of shellfish culture in the area, oyster production, occurs in nearshore locations far enough away from the three alternative sites that it should not be impacted in any manner by this proposed action. Finally, none of the disposal site options are in an area of special scientific importance; in fact, areas with such characteristics were screened out very early in the alternatives screening process. Accordingly, depositing dredged material at any of the three sites will not interfere with any of the activities described in this criterion or other legitimate uses of Long Island Sound.

ix. The Existing Water Quality and Ecology of the Sites as Determined by Available Data or by Trend Assessment or Baseline Surveys (40 CFR 228.6(a)(9)).

EPA's analysis of existing water quality and ecological conditions at the site in light of available data, trend assessments and baseline surveys indicates that use of the designated disposal sites will cause no unacceptable or unreasonable adverse environmental effects. Considerations related to water quality and various ecological factors (*e.g.,* sediment quality, benthic organisms, fish and shellfish) have already been discussed above in relation to other site selection criteria, and are discussed in detail in the DSEIS and supporting documents. In considering this criterion, EPA took into account existing water quality and sediment quality data collected at the disposal sites, including from the USACE's DAMOS site monitoring program, as well as water quality data from the Department of Energy and Environmental Protection's (CT DEEP) Long Island Sound Water Quality Monitoring Program. As discussed herein, EPA has determined that placement of suitable dredged material at the disposal site alternatives should not cause any significant adverse environmental effects to water quality or to ecological conditions at the disposal sites. EPA and the USACE have prepared a draft SMMP for the ELDS to guide future monitoring of site conditions (DSEIS Appendix I), and would prepare SMMPs for the NBDS and/or CSDS if either of them were to be designated.

x. Potentiality for the Development or Recruitment of Nuisance Species in the Disposal Sites (40 CFR 228.6(a)(10)).

Monitoring at disposal sites in Long Island Sound over the past 35 years has shown no recruitment of nuisance (invasive, non-native) species and no such adverse effects are expected to occur at the ELDS, NBDS, or CSDS in the future. EPA and the USACE will continue to monitor EPA-designated sites under their respective SMMPs, which include a "management focus" on "changes in composition and numbers of pelagic, demersal, or benthic biota at or near the disposal sites" (section 6.1.5 of the SMMP, Appendix I of the DSEIS).

xi. Existence at or in Close Proximity to the Sites of Any Significant Natural or Cultural Feature of Historical Importance (40 CFR 228.6(a)(11)).

There are no natural features of historical importance in the ELDS, NBDS, or CSDS, and the cultural resources that have the greatest potential for being impacted in eastern Long Island Sound are shipwrecks. As discussed in the DSEIS, a review of submerged vessel reports in the NOAA and Connecticut State Historic Preservation Office (CT SHPO) shipwreck databases indicate that there are three charted shipwrecks within 0.5

nmi (0.9 km) of the alternative sites. One of these charted shipwrecks is located within Site NL-Wa of the ELDS; this wreck was also identified by the side-scan sonar survey. The side-scan sonar survey identified two additional wrecks within the 0.5-nm (0.9-km) perimeter outside of the NBDS. None of these known shipwrecks are currently considered to be of historical significance. Consultation with the New York Office of Parks, Recreation and Historic Preservation (OPRHP; acts as the NY SHPO) revealed that there are no submerged vessels or historic resources within the portion of the CSDS that is located in New York State waters.

As additional side-scan sonar surveys are conducted at the disposal sites in the future under the SMMPs, and if potential shipwrecks are identified, EPA will take appropriate action in cooperation with federal and state historic preservation officials in response to any significant cultural resources. The CT SHPO also determined that there are no known aboriginal artifacts at the ELDS, NBDS, or CSDS. EPA coordinated with Indian tribes in Connecticut, Rhode Island, and New York throughout the development of the DSEIS and the tribes did not identify any important natural, cultural, spiritual, or historical features or areas within any of the three disposal sites under consideration.

In summary, there are no historic or archaeological resources within the NBDS or CSDS, and while the NL-Wa portion of the ELDS contains a shipwreck near its southern boundary, this wreck is not considered to be of historical significance. Nevertheless, any impacts to that wreck from dredged material disposal could be minimized by establishing a 164-foot (50 m) avoidance buffer surrounding the shipwreck and appropriate site management, which accommodates both the minimum buffer of 30 m recommended by the CT SHPO, and the 40–50 m minimum buffer applied by the NY OPRHP.

3. Disposal Site Management (40 CFR 228.3, 228.7, 228.8 and 228.9)

The ELDS, NBDS, and CSDS would be subject to specific management requirements to ensure that unacceptable adverse environmental impacts do not occur. Examples of these requirements include: (1) Restricting the use of the sites to the disposal of dredged material that has been determined to be suitable for ocean disposal following MPRSA and/or CWA requirements in accordance with the provisions of MPRSA section 106(f), as well as to material from waters in the vicinity of the disposal sites; (2) monitoring the disposal sites and their associated reference sites, which are not used for dredged material disposal, to assess potential impacts to the marine environment by providing a point of comparison to an area unaffected by dredged material disposal; and (3) retaining the right to limit or close these sites to further disposal activity if monitoring or other information reveals evidence of unacceptable adverse impacts to the marine environment. As mentioned above, dredged material disposal will not be allowed when weather and sea conditions could interfere with safe, effective placement of any dredged material at a designated site. In addition, although not technically a site management requirement, disposal activity at the sites will generally be limited to the period between October 1 and April 30, but often less depending on environmental windows to protect certain species, as described above.

EPA and the USACE have managed and monitored dredged material disposal activities at the CSDS and the historically used portion of the ELDS since the early 1980s. Site monitoring has been conducted under the USACE's DAMOS disposal site monitoring program. In accordance with the requirements of MPRSA section 102(c) and 40 CFR 228.3, EPA and the USACE have developed a draft SMMP for the ELDS, and are prepared to do so for the NBDS and/or CSDS if a decision is made to propose either for designation. The draft SMMP is incorporated in the DSEIS as Appendix I and is available for review and comment. The SMMP describes in detail the specific management and monitoring requirements for the ELDS. With respect to site monitoring, the SMMP builds on the USACE's DAMOS monitoring program, which will continue to provide the backbone of the site monitoring effort.

B. National Environmental Policy Act

The NEPA, 42 U.S.C. 4321 *et seq.*, requires the public analysis of the potential environmental effects of proposed federal agency actions and reasonable alternative courses of action to ensure that these effects, and the differences in effects among the different alternatives, are understood. The goal of this analysis is to ensure high quality, informed decision-making, to facilitate avoiding or minimizing any adverse effects of proposed actions, and to help restore and enhance environmental quality. *See* 40 CFR 6.100(a) and 1500.1(c) and 1500.2(d)–(f). NEPA requires public involvement throughout the decision-making process. *See* 40 CFR 6.400(a) and 40 CFR 1503 and 1501.7, 1506.6.

Section 102(c) of NEPA, 42 U.S.C. 4321 *et seq.*, requires federal agencies to prepare an EIS for major federal actions significantly affecting the quality of the human environment. An EIS should assess: (1) The environmental impact of the proposed action; (2) any adverse environmental effects that cannot be avoided should the proposal be implemented; (3) alternatives to the proposed action; (4) the relationship between local short-term uses of the environment and the maintenance and enhancement of long-term productivity; and (5) any irreversible and irretrievable commitments of resources that would be involved in the proposed action should it be implemented. The required content of an EIS is further described in regulations promulgated by the President's Council on Environmental Quality (CEQ). *See* 40 CFR 1502.

EPA disposal site designation evaluations conducted under the MPRSA have been determined to be "functionally equivalent" to NEPA reviews, so that they are not subject to NEPA analysis requirements as a matter of law. Nevertheless, as a matter of policy, EPA voluntarily uses NEPA procedures when evaluating the potential designation of ocean dumping sites. *See* 63 FR 58045 (Notice of Policy and Procedures for Voluntary Preparation of National Environmental Policy Act Documents, October 29, 1998). While EPA voluntarily uses NEPA review procedures in conducting MPRSA disposal site designation evaluations, EPA also has explained that "[t]he voluntary preparation of these documents in no way legally subjects the Agency to NEPA's requirements" (63 FR 58046).

In this case, EPA has prepared a Draft Supplemental EIS (DSEIS) to evaluate the possibility of designating one or more open-water disposal sites to serve the eastern Long Island Sound region. As previously noted, the DSEIS is considered supplemental because it updates and builds on the analyses that were conducted for the 2005 Long Island Sound Environmental Impact Statement that supported the designation of the Central and Western Long Island Sound disposal sites. As part of the NEPA process, federal agencies prepare a public record of decision (ROD) at the time of their final decision on any action for which an FEIS has been prepared. If EPA decides to proceed with this proposed action after full consideration of public comments, the Agency will publish a final rule (in conjunction with the FEIS) that will serve as the ROD for the site designation. *See* 40 CFR 1505.2 and 1506.4 (the ROD may be integrated into any other agency document prepared in carrying out its action). In addition, EPA will also publish a Responses to Comments document in conjunction with publication of a FSEIS and final rule. The Responses to Comments will identify and respond to comments received on the DSEIS and proposed rule. EPA's use of NEPA procedures to evaluate this proposed action is further described below.

Consistent with its voluntary NEPA policy, as described and referenced above, EPA has followed the NEPA process and undertaken NEPA analyses as part of its decision-making process for the disposal site designations. EPA published a Notice of Intent to prepare an EIS, held public meetings regarding the scope of issues to be addressed by the SEIS, and has now published a DSEIS for public review and comment. The DSEIS, entitled, "Draft Supplemental Environmental Impact Statement for the Designation of Dredged Material Disposal Site(s) in Eastern Long Island Sound, Connecticut and New York," assesses and compares the effects, including the environmental effects, of designating dredged material disposal sites in eastern Long Island Sound, and of various alternative approaches to managing dredging needs, including the "no action" alternative (*i.e.,* the alternative of not designating any open-water disposal sites). *See* 40 CFR 1502.14.

1. Third-Party Contracting

EPA is the agency authorized by the MPRSA to designate dredged material disposal sites and is responsible for the DSEIS. However, EPA does not receive appropriations to support disposal site designation studies, so the state of Connecticut provided funding to hire contractors to carry out the studies, support the public participation program, and help to produce the DSEIS, all with participation and close supervision by EPA. CEQ regulations state that an EIS can be prepared by a contractor under contract to and paid directly by the applicant (*i.e.,* a "third-party contract"). 40 CFR 1506.5(c); Forty Most Asked Questions Concerning CEQ's National Environmental Policy Act Regulations, 46 FR 18026, 18031 (1981). The contractor answers to the federal agency preparing the EIS (in this case, the EPA), not the applicant, for preparing an EIS that meets the requirements of the National Environmental Policy Act (NEPA). 40 CFR 1506.5(c).

Because EPA is ultimately responsible for the SEIS, the Agency worked closely with the state of Connecticut to select the contractors and then maintained close involvement with production of the SEIS and control over its analyses and conclusions. The state of Connecticut is not an "applicant" because it is not applying directly for the disposal site designation. Nevertheless, because Connecticut has expressed past support for designating one or more dredged material disposal sites in the eastern region of Long Island Sound, EPA followed the third-party contracting method described in 40 CFR 1506.5 to ensure the impartiality of the EIS.

Under the third-party contracting method, EPA must be involved in the selection of the contractor, furnish guidance and participate in the preparation of the EIS, and independently evaluate the EIS prior to approval. *See* 40 CFR 1506.5(c). The third-party contracting process used by EPA requires the third party (or parties) to pay for the contractor's services while EPA retains control of and supervisory authority over the analysis. *See* 66 FR 15527, 15531 (2001). While EPA retains final control over the selection of the contractor, applicants are allowed some input. *Id.* Once a contractor is selected, EPA and the applicant enter into a Memorandum of Understanding (MOU) outlining a general timeframe for the completion of the EIS and defining the scope of the EIS. *Id.* If EPA determines more information is needed, the MOU may be amended or EPA can complete the analysis itself. *Id.* The applicant and the contractor also enter into an agreement. *Id.* Additionally, the contractor must sign a disclosure statement for EPA declaring that it has no financial or other interest in the outcome of the project. *Id.;* 46 FR at 18031; 40 CFR 6.604(g)(3)(ii).

The Connecticut Department of Transportation (CT DOT) was the lead agency for the state with regard to preparation of the DSEIS, with technical assistance provided by the CT DEEP. CT DOT, with extensive input from EPA and CT DEEP, selected as its primary contractor the University of Connecticut, in large part due to its expertise in physical oceanography. The university selected as its subcontractor the Louis Berger Group (LBG). EPA worked in close partnership with CT DOT to ensure both that all project components carried out through third-party contracting would meet federal statutory and regulatory requirements, and that CT DOT's contractors were qualified to support public participation and other necessary processes under NEPA and the MPRSA, including scoping and site screening.

The U.S. Navy also contributed to the site designation process by funding biological and other environmental studies in support of the DSEIS. The Navy, with extensive input from EPA and CT DEEP, used its contractor Tetra Tech due to its expertise in biological resources studies and risk assessment.

2. Cooperating Agencies

The USACE was a "cooperating agency" in the development of the DSEIS because of its knowledge concerning the region's dredging needs, its technical expertise in monitoring dredged material disposal sites and assessing the environmental effects of dredging and dredged material disposal, its history in the regulation of dredged material disposal in Long Island Sound and elsewhere, and its ongoing legal role in regulating dredging, dredged material disposal and the management and monitoring of disposal sites. Other cooperating agencies were NMFS, CT DEEP, CT DOT, New York Department of State (NY DOS), New York Department of Environmental Conservation (NY DEC), and Rhode Island Coastal Resources Management Council (RI CRMC). To take advantage of expertise held by other entities, and to promote strong inter-agency communications, EPA also coordinated with the U.S. Fish and Wildlife Service; the Mashantucket (Western) Pequot Tribal Nation, Mohegan Tribe, Eastern Pequot Tribal Nation, and Paucatuck Eastern Pequot Indians (in Connecticut); the Narragansett Indian Tribe (in Rhode Island); the Shinnecock Indian Nation (in New York), and, as previously discussed, the CT SHPO and NY OPRHP.

Throughout the SEIS development process, EPA communicated with the cooperating federal and state agencies and tribes to keep them apprised of progress on the project and to solicit input. EPA conducted approximately ten interagency meetings and teleconferences between October 2012 and January 2016 to review progress and get feedback, and EPA was in regular contact with representatives of these agencies throughout the SEIS process.

3. Public Participation

Consistent with the public participation provisions of the NEPA regulations, EPA conducted an extensive public participation program throughout the development of the DSEIS as described in detail in Chapter 7 and Appendix A of the DSEIS.

4. Zone of Siting Feasibility

As one of the first steps in the SEIS process, EPA, in cooperation with other federal and state agencies delineated a "Zone of Siting Feasibility" (ZSF). The ZSF is the geographic area from which reasonable and practicable open-water dredged material disposal site alternatives should be selected for evaluation. EPA's 1986 site designation guidance manual describes the factors that should be considered in delineating the ZSF and recommends locating open-water disposal sites within an economically and operationally feasible radius from areas where dredging occurs. Other factors to be considered include navigational restrictions, political or other jurisdictional boundaries, the distance to the edge of the continental shelf, the feasibility of surveillance and monitoring, and operation and transportation costs. In 2012, consistent with the guidance and in cooperation with the other agencies, EPA established the ZSF to include the eastern region of Long Island Sound, with a western boundary consisting of a line from Mulberry Point in Guilford, CT, to Mattituck Point in Mattituck, NY, a southern boundary from Montauk Point to the southern tip of Block Island, and an eastern boundary from the northern tip of Block Island due north to the Rhode Island shoreline.

5. Draft Supplemental Environmental Impact Statement

The DSEIS evaluates whether—and if so, which—open-water dredged material disposal sites should be designated in the eastern region of Long Island Sound. The DSEIS describes the purpose and need for any such designations, evaluates several alternatives to this action, including the option of "no action" (*i.e.,* no designation). From this evaluation, EPA concludes that designation of the ELDS under the MPRSA is the preferred alternative.

The purpose of this designation is to provide a long-term, open-water dredged material disposal site as a potential option for the future disposal of such material. The action is necessary because periodic dredging and dredged material disposal is unavoidably necessary to maintain safe navigation and marine commerce in Long Island Sound. As previously noted, dredging in eastern Long Island Sound is projected to generate approximately 22.6 million cubic yards (mcy) of dredged material over the next 30 years, including 17.9 mcy from Connecticut ports and harbors and 4.7 mcy from ports and harbors in New York. Of the total amount of 22.6 mcy, approximately 13.5 mcy are projected to be suitable, fine-grained sediment, and 9.1 mcy are projected to be suitable, coarse-grained sand. In addition, the DMMP estimates that approximately 80,900 cy of material from eastern Long Island Sound will be fine-grained sediment that does not meet MPRSA and CWA standards for aquatic disposal (*i.e.,* "unsuitable" material).

With the USACE's DMMP as its primary source, EPA evaluated potential alternatives to open-water disposal in Long Island Sound but determined that they are not sufficient to meet the regional dredging needs. In accordance with EPA regulations, use of alternatives to open-water disposal will be required for dredged material management when they provide a practicable, environmentally preferable option for the dredged material from any particular disposal project. *See* 40 CFR 227.16. When no such practicable alternatives exist, however, EPA's designation of the ELDS will provide an open-water disposal site as a potential management option for dredged material regulated under the MPRSA that has been tested and determined to be environmentally suitable for open-water disposal. Sediments found to be unsuitable for open-water disposal will not be authorized for placement at a disposal site designated by EPA under the MPRSA and will have to be managed in other ways.

EPA's initial screening of alternatives, which involved input from other federal and state agencies, local governments, academic institutions, and the public, led to the determination that the open-water disposal sites were the most environmentally sound, cost-effective, and operationally feasible options for the full quantity of dredged material expected to be found suitable for open-water disposal over the 30-year planning horizon. Regardless of this conclusion, in practice, each individual dredging project will be analyzed on a case-specific basis and open-water disposal of dredged material at a designated site would only be authorized when there is a need for such disposal (*i.e.,* there are no practicable, environmentally preferable alternatives). *See* 40 CFR 227.2(a)(1), 227.16(b). EPA analyzed alternatives for the management of dredged material from navigation channels and harbors in eastern Long Island Sound. This analysis was informed by the DMMP and evaluated several different potential alternatives, including open-water disposal sites, upland disposal, beneficial uses, sediment treatment, and the no-action alternative. From this analysis, EPA determined that at least one open-water disposal site, such as the ELDS, was necessary to provide sufficient capacity to meet long-term dredged material disposal needs in the eastern Long Island Sound region, in the event that practicable alternatives to open-water disposal are not available for all the material. Again, EPA's analysis also acknowledged that options for dredged material management other than open-water disposal might be identified and required for specific dredged material disposal projects in the future.

EPA also evaluated several open-water disposal site alternatives other than the ELDS, NBDS, and CSDS. This evaluation considered multiple factors, such as reasonable distances to transport dredged material, the potential for adverse effects on important natural resources, and other measures that might indicate incompatibility for use as a disposal site. Specific factors evaluated included: The sensitivity and value of natural resources; geographically limited habitats; fisheries and shellfisheries; shipping and navigation lanes; physical and environmental parameters; and economic and operational feasibility. The analysis was carried out in a tiered process in which some options were "screened out" at an earlier stage based on certain factors, while other options were retained for further evaluation. The final tier involved a detailed analysis of the no-action alternative and the following three open-water alternative sites: ELDS, NBDS, and CSDS. Based on this analysis, designating the ELDS as an open-water dredged material disposal site was identified as the preferred alternative, but we are soliciting public comments on the other two alternative sites (NBDS and CSDS). A management and monitoring strategy was developed for the ELDS and is set forth in the SMMP for the site.

C. Coastal Zone Management Act

The CZMA, 16 U.S.C. 1451 *et seq.,* authorizes states to establish coastal zone management programs to develop and enforce policies to protect their coastal resources and promote uses of those resources that are desired by the state. These coastal zone management programs must be approved by the Department of Commerce's National Oceanic and Atmospheric Administration (NOAA), which is responsible for administering the CZMA. Sections 307(c)(1)(A) and (C) of the CZMA require federal agencies to provide relevant states with a determination that each federal agency activity, whether taking place within or outside the coastal zone, that affects any land or water use or natural resource of the state's coastal zone, will be carried out in a manner consistent to the maximum extent practicable with the enforceable policies of the state's approved coastal zone management program. EPA's compliance with the CZMA is described below.

Based on the evaluations presented in the DSEIS and supporting documents, and a review of the federally approved Connecticut and New York coastal zone programs and policies, EPA has determined that designation of the ELDS, and/or the NBDS and CSDS for open-water dredged material disposal under the MPRSA would be consistent to the maximum extent practicable with the enforceable policies of the coastal zone management programs of Connecticut, New York, and Rhode Island. EPA will provide a written determination to that effect to each of the three states within the statutory and regulatory mandated timeframes.

In EPA's view, there are several broad reasons why the proposed designation of the ELDS would be consistent with the applicable, enforceable policies of both states' coastal zone programs. First, the designation is not expected to cause any significant adverse impacts to the marine environment, coastal resources, or uses of the coastal zone. Indeed, EPA expects the designation to benefit uses involving navigation and berthing of vessels by facilitating needed dredging, and to benefit the environment by concentrating any open-water dredged material disposal at a small number of environmentally appropriate sites designated by EPA and subject to the previously described SMMP, rather than at a potential proliferation of USACE-selected sites. Second, designation of the sites does not actually authorize the disposal of any dredged material at the sites, since any proposal to dispose dredged material from a particular project at a designated site will be subject to case-specific evaluation and be allowed only if: (a) The material satisfies the sediment quality requirements of the MPRSA and the CWA; (b) no practicable alternative method of management with less adverse environmental impact can be identified; and (c) the disposal complies with the site restrictions for the site. (EPA is proposing a number of restrictions on the potential use of the ELDS in today's Proposed Rule. *See* Proposed 40 CFR 228.15(b)(6)). These restrictions are described and discussed in the next section of the preamble. Third, the designated disposal site(s) will be managed and monitored pursuant to a SMMP and if adverse impacts are identified, use of the sites will be modified to reduce or eliminate those impacts. Such modification could further restrict, or even terminate, use of the sites, if appropriate. *See* 40 CFR 228.3, 228.11.

On December 22, 2015, as suggested by NOAA guidance on federal consistency determinations, EPA sent letters to NY DOS and CT DEEP (1) identifying EPA's effort to prepare a DSEIS to assess whether to propose designation of one or more dredged material disposal sites in the eastern portion of Long Island Sound, and (2) requesting information from each state concerning their respective coastal zone management programs to assist EPA with its federal consistency determination. On March 11, 2016, EPA sent a similar letter to the State of Rhode Island Coastal Resources Management Council. All three states responded in writing to EPA's letters and provided the most current information on their respective coastal management programs.

D. Endangered Species Act

Under section 7(a)(2) of the ESA, 16 U.S.C. 1536(a)(2), federal agencies are required to ensure that their actions are "not likely to jeopardize the continued existence of any endangered species or result in the destruction or adverse modification of habitat of such species, which is determined * * * to be critical * * * ." Depending on the species involved, a federal agency is required to consult with the NMFS and/or USFWS if the agency's action "may affect" an endangered or threatened species or its critical habitat (50 CFR 402.14(a)). Thus, the ESA requires consultation with NMFS and/or USFWS to adequately address potential impacts to threatened and endangered species that may occur at the proposed dredged material disposal alternative sites from any proposal to dispose dredged material.

To comply with the ESA, EPA has coordinated with NMFS and USFWS and will request consultation concurrent with the release of the draft SEIS. EPA has determined that the designation of a disposal site will not result in adverse impacts to threatened or endangered species, species of concern, marine protected areas, or essential fish habitat. In addition, the USACE would coordinate with the NMFS and USFWS for individual permitted projects to further ensure that impacts would not adversely impact any threatened or endangered species.

E. Magnuson-Stevens Fishery Conservation and Management Act

The 1996 Sustainable Fisheries Act amendments to the MSFCMA, 16 U.S.C. 1801 *et seq.*, require the designation of essential fish habitat (EFH) for federally managed species of fish and shellfish. The goal of the these amendments is to ensure that EFH is not adversely impacted by fishing or other human activities, including dredged material disposal, and to further the enhancement of these habitats, thereby protecting both ecosystem health and the fisheries industries. Pursuant to section 305(b)(2) of the MSFCMA, federal agencies are required to consult with NMFS regarding any action they authorize, fund, or undertake that may adversely affect EFH. An adverse effect has been defined by the Act as, "[a]ny impact which reduces the quality and/or quantity of EFH [and] may include direct (*e.g.*, contamination or physical disruption), indirect (*e.g.*, loss of prey, reduction in species' fecundity), site-specific or habitat-wide impacts, including individual, cumulative, or synergistic consequences of actions" (50 CFR 600.810(a)).

EPA is coordinating with NMFS to ensure compliance with the EFH provisions of the MSFCMA and has prepared an essential fish habitat assessment in compliance with the Act. EPA will incorporate any conservation recommendations from NMFS or explain why it has not done so in its final action.

VI. Restrictions

EPA proposes to restrict use of the ELDS in the same manner that it has restricted use of the CLDS and WLDS. The existing site use restrictions for the CLDS are detailed in 40 CFR 228.15(b)(4)(vi) and are incorporated for the WLDS by the cross-references in 40 CFR 228.15(b)(4)(vi) and 228.15(b)(5)(vi). Similarly, EPA is proposing to apply to the ELDS the same restrictions as are applied to the CLDS and WLDS by including simple cross-references to those restrictions in the new proposed regulations at 40 CFR 228.15(b)(4) and 228.15(b)(6)(vi).

While EPA is planning for the restrictions applicable to the CLDS and WLDS to also be applied to the ELDS, it also should be understood that EPA is currently proposing amendments to the CLDS/WLDS restrictions. Specifically, on February 10, 2016, EPA published in the **Federal Register** (81 FR 7055) a proposed rule to *amend* the restrictions on the CLDS and WLDS. EPA is currently considering public comments received on the proposed regulatory amendments.

EPA has proposed amendments to the CLDS/WLDS restrictions in order to incorporate new standards and procedures for the use of those sites consistent with the recommendations of the Long Island Sound DMMP completed by the USACE on January 11, 2016. The DMMP identifies a wide range of alternatives to open-water disposal and recommends standards and procedures to help determine whether and which of these alternatives should be pursued for particular dredging projects. The goal of EPA's proposed regulatory amendments based on these standards and procedures is to reduce or eliminate the open-water disposal of dredged material in Long Island Sound wherever practicable.

The DMMP addresses dredging and dredged material management issues for *all* of Long Island Sound, including the eastern portion of the Sound. Therefore, EPA concludes that it makes sense to apply site use restrictions based on the DMMP to the ELDS as well as to the CLDS and WLDS. Again, it is intended that these restrictions will help to reduce or eliminate dredged material disposal in the Eastern portion of Long Island Sound as well as in the Central and Western portions. That said, no final decisions have been made about final restrictions for the ELDS and such final decisions will only be made after EPA considers public comments received on this proposed rule and other relevant information.

In order to understand the nature of the site use restrictions that EPA is considering for the ELDS, reviewers of this proposed rule for the ELDS should review the site use restrictions in 40 CFR 228.15(b)(4)(vi), as cross-referenced in proposed 40 CFR 228.15(b)(6)(vi). Reviewers can also review the regulatory amendments that EPA has proposed for 40 CFR 228.15(b)(4)(vi). *See* 81 FR 7055. EPA is currently considering public comments submitted on these proposed amendments and, as explained above, EPA expects that the amendments, including any changes made to them based on public comments, will ultimately be applied to the ELDS, as well as to the CLDS and WLDS. This expectation is, however, subject to EPA considering the final amendments to the restrictions for the CLDS and WLDS, public comments received on this proposed rule for the ELDS, and other relevant information. The proposed restrictions on site use are summarized below.

A. Standards

The proposed restrictions provide that disposal at the site shall be allowed only if there is no practicable alternative to open-water disposal and that any practicable alternative will be fully utilized for the maximum volume of dredged material practicable. EPA recognizes that an alternative to open-water disposal may add additional costs. The decision regarding whether there is a "practicable alternative" will continue to be made on a case-by-case basis, in connection with the permitting process. The term "practicable alternative" is defined in 40 CFR 227.16(b) of the EPA's ocean disposal regulations as an alternative which is "available at reasonable incremental cost and energy expenditures, [and] which need not be competitive with the costs of ocean dumping, taking into account the environmental benefits derived from such activity, including the relative adverse environmental impacts associated with the use of alternatives to ocean dumping."

The following standards for the disposal of dredged material, by type of material, are derived from the DMMP. These proposed restrictions do not make decisions about the suitability of any particular dredged material for open-water disposal or any other type of management. Each dredging project will have to go through project-specific permitting evaluations.

1. Unsuitable Material

"Unsuitable fine-grained materials" are those determined by physical, chemical and biological testing to be unsuitable for unconfined open-water placement. Accordingly, EPA's proposed rule specifies that unsuitable fine-grained materials shall not be disposed of at the designated sites.

2. Sandy Material

"Sandy material" in Long Island Sound is coarse-grained material of generally up to 20 percent fines when used for direct beach placement, or up to 40 percent fines when used for nearshore bar/berm nourishment. Clean sandy material should be used for beach or nearshore bar/berm nourishment whenever practicable. Sandy material has a high value as nourishment or in other coastal resiliency applications, and recent experience is that state and local governments, as well as property owner groups, are willing to fund the additional cost for such material even where there is no other federal project authority to assist in that cost. As long as beach or nearshore placement is a practicable alternative, project proponents will need to identify and secure funding for any needed non-federal cost-sharing. Accordingly, the proposed restriction specifies that coarse-grained material should be used for beach or nearshore bar/berm nourishment, or other beneficial use whenever practicable.

3. Suitable Fine-Grained Material

"Suitable fine-grained material" in Long Island Sound is typically clay and silty material of more than 20 to 40 percent fines that is not suitable for beach or nearshore placement, yet is determined through testing and analysis to be suitable for open-water placement. Although the most likely cost-effective and environmentally acceptable method of placement of this material is at open-water disposal sites, EPA proposes that every proposed project will continue to have to exhaust the possibility for a practicable alternative to open-water disposal. More specifically, for materials dredged from upper river channels in the Connecticut, Housatonic and Thames Rivers, whenever practicable, the one existing Confined Open Water site, and on-shore or in-river placement, should be used for such projects.

The proposed restrictions specify that beneficial uses such as marsh creation, should be examined and used whenever practicable. If no other alternative is determined to be practicable, suitable fine-grained material may be placed at the designated site.

4. Source Reduction

Efforts to control sediment entering waterways can reduce the need for maintenance dredging of harbor features and facilities by reducing shoaling rates. Reducing sediment loads could help reduce the volumes dredged in each maintenance operation as well as reduce the frequency of maintenance. In addition, efforts to prevent introduction of contaminants into the watershed (*e.g.,* multi-sector and municipal stormwater permits, measures to control nonpoint agricultural runoff) can result in reduced contaminant levels in sediments that can increase the range of options available to beneficially use those sediments. Continued source reduction efforts for both sediment and contaminants will assist in further reducing the need for open-water placement of dredged material in Long Island Sound. The EPA expects that federal, state and local agencies tasked with regulating those discharges into the watersheds tributary to Long Island Sound will exercise their authority under various statues and regulations in a continuing effort to reduce the flow of sediments and contaminants into state waterways and harbors.

B. Procedures

The Long Island Sound Regional Dredging Team (RDT) was formed to identify practicable alternatives to open-water disposal and recommend their use for projects proposed while the USACE was preparing the DMMP. EPA proposes to include restrictions that redefine the role of the RDT to ensure that the Standards described above are utilized in evaluating proposed dredging projects in Long Island Sound. EPA proposes restrictions that make explicit the RDT's purpose, geographic scope, membership, structure and general process as described below.

1. Purpose of the Long Island Sound Regional Dredging Team (LIS RDT)

The primary purpose of the LIS RDT is to reduce or eliminate wherever practicable the open-water disposal of dredged material in Long Island Sound. The LIS RDT will accomplish this by reviewing all proposed dredging projects subject to MPRSA (namely all federal projects and non-federal projects that generate greater than 25,000 cubic yards) to assess whether there are practicable alternatives to open-water disposal, by recommending that any available alternative(s) to open-water disposal be utilized for the maximum volume of dredged material practicable, and to provide documented findings and recommendations to USACE on these points so that the USACE and the EPA can consider the LIS RDT's recommendations. The LIS RDT should review the alternatives analysis for all projects submitted to help ensure that available alternatives as described in the DMMP for each harbor and dredging center have been thoroughly evaluated and are implemented where practicable. While the LIS RDT will conduct project reviews and make submissions and recommendations to the USACE, the LIS RDT will not supplant the regulatory obligations or authorities of participant agencies under the MPRSA, CWA, CZMA or other applicable laws.

Other purposes of the LIS RDT include: Serving as a forum for continuing exploration of new beneficial use alternatives to open-water disposal; promoting the use of such alternatives; and suggesting approaches for cost-sharing opportunities. For example, the LIS RDT could further investigate and develop opportunities for approving and funding long-term regional Confined Disposal Facilities which could accommodate suitable and unsuitable dredged material and provide environmental and social benefits such as parkland and habitat once filled and closed.

The LIS RDT and its member agencies should also assist USACE and EPA in continuing a number of long term activities to continue the environmentally sound implementation of dredging and dredged material management in Long Island Sound. These activities include supporting USACE's dredged material tracking system, supporting USACE's DAMOS (Disposal Area Monitoring System) program and related efforts to study the long-term impacts of open-water placement, and promoting opportunities for beneficial use of clean, parent marine sediments often generated in the development of CAD cells.

2. Geographic Scope

The geographic range of the LIS RDT will include all of Long Island Sound and adjacent waters landward of the seaward edge of the territorial sea (three mile limit) or, in other words, from Throgs Neck to a line three miles east of the baseline across western Block Island Sound. These boundaries would encompass all harbors and areas included in the DMMP except Block Island. The WLDS, CLDS, and ELDS would all be within the RDT's purview.

3. Membership

The LIS RDT should include representatives from affected federal and state government organizations. EPA anticipates that federal participation would include EPA Regions 1 & 2; the New England and New York Districts and the North Atlantic Division of the USACE and the National Oceanic and Atmospheric Administration. EPA encourages the participation of the U.S. Navy, the U.S. Coast Guard and the U.S. Fish & Wildlife Service. EPA expects that the states of Connecticut, New York and Rhode Island would be participants through their environmental agencies, coastal zone management programs and relevant port authorities. EPA requests that, to the extent possible, member organizations will provide sufficient funding to enable their active participation in the LIS RDT.

4. Structure and Process

EPA proposes that the specific details for structure (*e.g.*, chair, committees, working groups) and process (*e.g.*, how projects come before the LIS RDT, coordination with other entities) be left for the LIS RDT to determine and allowed to evolve as best accomplishes the team's purpose.

The LIS RDT is encouraged to establish and maintain cooperative working relationships with other Long Island Sound-based organizations (*e.g.*, the Long Island Sound Study's Science and Technical Advisory Committee, non-governmental organizations, relevant university-based programs) so that relevant scientific, program and policy information is effectively shared and resources are leveraged to the maximum extent.

VII. Proposed Action

EPA is proposing this rule to designate the ELDS for the purpose of providing an environmentally sound, open-water disposal option for possible use in managing dredged material from harbors and navigation channels in eastern Long Island Sound and its vicinity in the states of Connecticut, New York, and Rhode Island. Without this dredged material disposal site designation, there will be no open-water disposal site available in the eastern region of Long Island Sound after December 23, 2016. In developing the DMMP, described previously in several sections, the USACE conducted a "dredging needs" assessment that estimated that a total volume of 22.6 mcy of dredged material that from the eastern region of Long Island Sound over the 30-year planning horizon.

The site designation process has been conducted consistent with the requirements of the MPRSA, CWA, NEPA, CZMA, and other applicable federal and state statutes and regulations. The basis for this federal action is further described in a DSEIS that identifies EPA designation of the ELDS as the preferred alternative. The DSEIS also is being released for public comment in conjunction with the publication of this proposed rule. Upon completion of the public comment period and EPA's consideration of all comments received, EPA will publish a final Supplemental Environmental Impact Statement (FSEIS) specifying a preferred alternative, and a final rule that will serve as EPA's Record of Decision (ROD) in the NEPA process.

The ELDS is subject to management and monitoring protocols to prevent the occurrence of unacceptable adverse environmental impacts. These protocols are spelled out in a SMMP for the site. The SMMP is included as Appendix I to the DSEIS. Under 40 CFR 228.3(b), the Regional Administrator of EPA Region 1 is responsible for the overall management of this site. As previously explained, the designation of these disposal sites does not constitute or imply EPA's approval of open-water disposal at either site of dredged material from any specific project. Disposal of dredged material will not be allowed at the ELDS until the proposed disposal operation first receives proper authorization from the USACE under MPRSA section 103. In addition, any such authorization by the Corps is subject to EPA review under MPRSA section 103(c), and EPA may condition or "veto" the authorization as a result of such review in accordance with MPRSA section 103(c). In order to properly obtain authorization to dispose of dredged material at the ELDS disposal site under the MPRSA, the dredged material proposed for disposal must first satisfy the applicable criteria for testing and evaluating dredged material specified in EPA regulations at 40 CFR part 227, and it must be determined in accordance with EPA regulations at 40 CFR part 227, subpart C, that there is a need for open-water disposal (*i.e.*, that there is no practicable dredged material management alternative to open-water disposal with less adverse environmental impact). In addition, any proposal to dispose of dredged material under the MPRSA at the designated site will need to satisfy all the site Restrictions included in the final rule as part of the site designations. *See* 40 CFR 228.8 and 228.15(b)(6).

VIII. Supporting Documents

1. EPA Region 1/USACE NAE. 2005. Response to Comments on the Final Environmental Impact Statement for the Designation of Dredged Material Disposal Sites in Central and Western Long Island Sound, Connecticut and New York. U.S. Environmental Protection Agency, Region 1, Boston, MA and U.S. Army Corps of Engineers, New England District, Concord, MA. April 2005.

2. EPA Region 1. 2005. Memorandum to the File Responding to the Letter from the New York Department of State Objecting to EPA's Federal Consistency Determination for the Dredged Material Disposal Site Designations. U.S. Environmental Protection Agency, Region 1, Boston, MA. May 2005.

3. EPA Region 1/USACE NAE. 2004. Final Environmental Impact Statement for the Designation of Dredged Material Disposal Sites in Central and Western Long Island Sound, Connecticut and New York. U.S. Environmental Protection Agency, Region 1, Boston, MA and U.S. Army Corps of Engineers, New England District, Concord, MA. March 2004.

4. EPA Region 1/USACE NAE. 2004. Regional Implementation Manual for the Evaluation of Dredged Material Proposed for Disposal in New England Waters. U.S. Environmental Protection Agency, Region 1, Boston, MA, and U.S. Army Corps of Engineers, New England District, Concord, MA. April 2004.

5. EPA Region 2/USACE NAN. 1992. Guidance for Performing Tests on Dredged Material Proposed for Ocean Disposal. U.S. Environmental Protection Agency, Region 2, New York, NY and U.S. Army Corps of Engineers, New York District, New York, NY. Draft Release. December 1992.

6. EPA/USACE. 1991. Evaluation of Dredged Material Proposed for Ocean Disposal-Testing Manual. U.S. Environmental Protection Agency, Washington, DC, and U.S. Army Corps of Engineers, Washington, DC. EPA–503/8–91/001. February 1991.

7. Long Island Sound Study. 2015. Comprehensive Conservation and Management Plan for Long Island Sound. Long Island Sound Management Conference. September 2015.

8. NY DEC and CT DEP. 2000. A total maximum daily load analysis to achieve water quality standards for dissolved oxygen in Long Island Sound. Prepared in conformance with section 303(d) of the Clean Water Act and the Long Island Sound Study. New York State Department of Environmental Conservation, Albany, NY and Connecticut Department of Environmental Protection, Hartford, CT. December 2000.

9. USACE NAE. 2016. Final Long Island Sound Dredged Material Management Plan and Final Programmatic Environmental Impact Statement—Connecticut, Rhode Island and New York. U.S. Army Corps of Engineers, New England District. December 2015.

IX. Statutory and Executive Order Reviews

1. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action, as defined in the Executive Order, and was therefore not submitted to the Office of Management and Budget (OMB) for review.

2. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA because it would not require persons to obtain, maintain, retain, report or publicly disclose information to or for a federal agency.

3. Regulatory Flexibility Act (RFA)

This action will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (RFA). The amended restrictions in this proposed rule are only relevant for dredged material disposal projects subject to the MPRSA. Non-federal projects involving 25,000 cubic yards or less of material are not subject to the MPRSA and, instead, are regulated under CWA section 404. This action will, therefore, have no effect on such projects. "Small entities" under the RFA are most likely to be involved with smaller projects not covered by the MPRSA. Therefore, EPA does not believe a substantial number of small entities will be affected by today's rule. Furthermore, the proposed amendments to the restrictions also will not have significant economic impacts on a substantial number of small entities because they primarily will create requirements to be followed by regulatory agencies rather than small entities, and will create requirements (*i.e.*, the standards and procedures) intended to help ensure satisfaction of the existing regulatory requirement (*see* 40 CFR 227.16) that practicable alternatives to the ocean dumping of dredged material be utilized.

4. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

5. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Through the RDT process, however, this action will provide a vehicle for facilitating the interaction and communication of interested federal and state agencies concerned with regulating dredged material disposal in Long Island Sound.

6. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175 because the proposed restrictions will not have substantial direct effects on Indian tribes, on the relationship between the federal government and Indian Tribes, or the distribution of power and responsibilities between the federal government and Indian Tribes. EPA consulted with the potentially affected

Indian tribes in making this determination.

7. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

8. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

9. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

10. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes the human health or environmental risk addressed by this action will not have a disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations.

11. Executive Order 13158: Marine Protected Areas

Executive Order 13158 (65 FR 34909, May 31, 2000) requires EPA to "expeditiously propose new science-based regulations, as necessary, to ensure appropriate levels of protection for the marine environment." EPA may take action to enhance or expand protection of existing marine protected areas and to establish or recommend, as appropriate, new marine protected areas. The purpose of the Executive Order is to protect the significant natural and cultural resources within the marine environment, which means, "those areas of coastal and ocean waters, the Great Lakes and their connecting waters, and submerged lands thereunder, over which the United States exercises jurisdiction, consistent with international law."

The EPA expects that this proposed rule will afford additional protection to the waters of Long Island Sound and organisms that inhabit them. Building on the existing protections of the MPRSA and the ocean dumping regulations, the proposed regulatory amendments are designed to promote the reduction of open-water disposal of dredged material in Long Island Sound.

12. Executive Order 13547: Stewardship of the Ocean, Our Coasts, and the Great Lakes

Section 6(a)(i) of Executive Order 13547, (75 FR 43023, July 19, 2010) requires, among other things, EPA and certain other agencies ". . . to the fullest extent consistent with applicable law [to] . . . take such action as necessary to implement the policy set forth in section 2 of this order and the stewardship principles and national priority objectives as set forth in the Final Recommendations and subsequent guidance from the Council." The policies in section 2 of Executive Order 13547 include, among other things, the following: ". . . it is the policy of the United States to: (i) protect, maintain, and restore the health and biological diversity of ocean, coastal, and Great Lakes ecosystems and resources; [and] (ii) improve the resiliency of ocean, coastal, and Great Lakes ecosystems, communities, and economies . . . ." As with Executive Order 13158 (Marine Protected Areas), the overall purpose of the Executive Order is to promote protection of ocean and coastal environmental resources.

The EPA expects that this proposed rule will afford additional protection to the waters of Long Island Sound and the organisms that inhabit them. Building on the existing protections of the MPRSA and the ocean dumping regulations, the proposed regulatory amendments are designed to promote the reduction or elimination of open-water disposal of dredged material in Long Island Sound.

List of Subjects in 40 CFR Part 228

Environmental protection, Water pollution control.

Dated: April 18, 2016.

H. Curtis Spalding,

Regional Administrator, EPA Region 1—New England.

For the reasons stated in the preamble, title 40, Chapter I, of the *Code of Federal Regulations* is proposed to be amended as set forth below.

PART 228—CRITERIA FOR THE MANAGEMENT OF DISPOSAL SITES FOR OCEAN DUMPING

■ 1. The authority citation for part 228 continues to read as follows:

Authority: 33 U.S.C. 1412 and 1418.

■ 2. Section 228.15(b) is amended by revising paragraph (b)(4)(vi) introductory text and adding paragraph (b)(6) to read as follows:

§ 228.15 Dumping sites designated on a final basis.

* * * * *

(b) * * *

(4) * * *

(vi) *Restrictions:* The designation in this paragraph (b)(4) sets forth conditions for the use of the Central Long Island Sound (CLDS), Western Long Island Sound (WLDS) and Eastern Long Island Sound (ELDS) Dredged Material Disposal Sites. These conditions apply to all disposal subject to the MPRSA, namely, all federal projects and nonfederal projects greater than 25,000 cubic yards. All references to" permittees" shall be deemed to include the U. S. Army Corps of Engineers (USACE) when it is authorizing its own dredged material disposal from a USACE dredging project. The conditions for this designation are as follows:

* * * * *

(6) Eastern Long Island Sound Dredged Material Disposal Site (ELDS).

(i) *Location:* Corner Coordinates (NAD 1983) 41°15.81′ N., 72°04.57′ W.; 41°16.81′ N., 72°04.57′ W.; 41°16.81′ N., 72°07.22′ W.; 41°15.81′ N., 72°07.22′ W.

(ii) *Size:* A 2 by 1 nautical mile rectangular area, a size of 2 square nautical miles (nmi^2).

(iii) *Depth:* Ranges from 45 to 100 feet (14m to 30m).

(iv) *Primary use:* Dredged material disposal.

(v) *Period of use:* Continuing use.

(vi) *Restrictions:* See 40 CFR 228.15(b)(4)(vi)(A) through (N).

* * * * *

[FR Doc. 2016–09603 Filed 4–26–16; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 16–93, RM–11764; DA 16–404]

Television Broadcasting Services; Tolleson, Arizona

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission has before it a petition for rulemaking filed by America 51, L.P. (America 51), the licensee of KPPX–TV, channel 51, Tolleson, Arizona, requesting the substitution of channel 31 for channel 51 at Tolleson. While the Commission instituted a freeze on the acceptance of full power television rulemaking petitions requesting channel substitutions in May 2011, it subsequently announced that it would lift the freeze to accept such petitions for rulemaking seeking to relocate from channel 51 pursuant to a voluntary relocation agreement with Lower 700 MHz A Block licensees. America 51 has entered into such a voluntary relocation agreement with T-Mobile and states that operation on channel 31 would remove any potential interference with authorized wireless operations in the Lower 700 MHZ A Block adjacent to channel 51 in the Phoenix, Arizona market, permitting those operations to expand to additional consumers sooner than would otherwise be possible.

DATES: Comments must be filed on or before May 27, 2016, and reply comments on or before June 13, 2016.

ADDRESSES: You may submit comments, identified by MB Docket No. 16–93, by any of the following methods:

- *Federal Communications Commission's Web site: http://apps.fcc.gov/ecfs/.* Follow the instructions for submitting comments.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

FOR FURTHER INFORMATION CONTACT: Joyce Bernstein, *Joyce.Bernstein@fcc.gov,* Media Bureau, (202) 418–1647.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MB Docket No. 16–93, adopted April 14, 2016, and released April 14, 2016. The full text of this document is available for public inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY–A257, 445 12th Street SW., Washington, DC, 20554. This document will also be available via ECFS (*http://www.fcc.gov/cgb/ecfs/*). (Documents will be available electronically in ASCII, Word 97, and/or Adobe Acrobat.). To request this document in accessible formats (computer diskettes, large print, audio recording, and Braille), send an email to *fcc504@fcc.gov* or call the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY). This document does not contain proposed information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden "for small business concerns with fewer than 25 employees," pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding. Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts (other than *ex parte* presentations exempt under 47 CFR 1.1204(a)) are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1208 for rules governing restricted proceedings.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

Proposed Rule

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336, and 339.

§ 73.622 [Amended].

■ 2. Section 73.622(i), in the table under Arizona, is amended by adding channel 31 and removing channel 51 at Tolleson.

[FR Doc. 2016–09831 Filed 4–26–16; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 16–123, RM–11766; DA 16–405]

Television Broadcasting Services; Cordele, Georgia

AGENCY: Federal Communications Commission.

ACTION: Proposed Rule.

SUMMARY: The Commission has before it a petition for rulemaking filed by Sunbelt-South TeleCommunications, Ltd. (Sunbelt), the licensee of WSST–TV, channel 51, Cordele, Georgia, requesting the substitution of channel 22 for channel 51 at Cordele. While the Commission instituted a freeze on the acceptance of full power television rulemaking petitions requesting channel substitutions in May 2011, it subsequently announced that it would lift the freeze to accept such petitions for rulemaking seeking to relocate from channel 51 pursuant to a voluntary relocation agreement with Lower 700 MHz A Block licensees. Sunbelt has entered into such a voluntary relocation agreement with T-Mobile USA, Inc. and states that operation on channel 22 would remove any potential interference with authorized wireless operations in the Lower 700 MHZ A Block adjacent to channel 51.

DATES: Comments must be filed on or before May 27, 2016, and reply comments on or before June 13, 2016.

ADDRESSES: Federal Communications Commission, Office of the Secretary, 445 12th Street SW., Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve counsel for petitioner as follows: Scott C. Cinnamon, Esq., Law Offices of Scott C. Cinnamon, PLLC, 1250 Connecticut Avenue NW., Suite 200, #144, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Joyce Bernstein, *Joyce.Bernstein@fcc.gov,* Media Bureau, (202) 418–1647.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MB Docket No. 16–123, adopted April 14, 2016, and released April 14, 2016. The full text of this document is available for public inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY–A257, 445 12th Street SW., Washington, DC 20554. This document will also be available via ECFS (*http://www.fcc.gov/cgb/ecfs/*). (Documents will be available electronically in ASCII, Word 97, and/or Adobe Acrobat.). To request this document in accessible formats (computer diskettes, large print, audio recording, and Braille), send an email to *fcc504@fcc.gov* or call the Commission's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY). This document does not contain proposed information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden "for small business concerns with fewer than 25 employees," pursuant to the Small Business Paperwork Relief Act of

2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding. Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts (other than *ex parte* presentations exempt under 47 CFR 1.1204(a)) are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1208 for rules governing restricted proceedings.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

Proposed Rules

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336, and 339.

§ 73.622 [Amended]

■ 2. Section 73.622(i), the Post-Transition Table of DTV Allotments under Georiga is amended by adding channel 22 and removing channel 51 at Cordele.

[FR Doc. 2016–09830 Filed 4–26–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Parts 350

[Docket No. FMCSA–2014–0470]

RIN 2126–AB84

State Inspection Programs for Passenger-Carrier Vehicles

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Advance notice of proposed rulemaking (ANPRM).

SUMMARY: FMCSA announces that it is considering a rulemaking that would require the States to establish a program for annual inspections of commercial motor vehicles (CMVs) designed or used to transport passengers (or, passenger-carrying CMVs). FMCSA plans to assess the risks associated with improperly maintained or inspected passenger-carrying CMVs by reviewing the effectiveness of existing Federal inspection standards that are applicable to these types of vehicles, and considering the costs and benefits of having a mandatory inspection program.

DATES: Comments on this notice must be received on or before June 27, 2016.

ADDRESSES: You may submit comments identified by Docket Number FMCSA–2014–0470 using any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* 202–493–2251.

To avoid duplication, please use only one of these four methods. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Loretta Bitner, Chief, Passenger Carrier Division at 202–385–2428, or via email at *Loretta.Bitner@dot.gov,* Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION: This advanced notice of proposed rulemaking (ANPRM) is organized as follows:

I. Public Participation and Request for Comments
  A. Submitting Comments
  B. Viewing Comments and Documents
  C. Privacy Act
II. Legal Basis for the Rulemaking
III. Background
IV. Questions

I. Public Participation and Request for Comments

A. Submitting Comments

If you submit a comment, please include the docket number for this ANPRM (Docket No. FMCSA–2014–0470), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* put the docket number, FMCSA–2014–0470, in the keyword box, and click "Search." When the new screen appears, click on the "Comment Now!" button and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and material received during the comment period and may develop a notice of proposed rulemaking (NPRM) based on your comments and other information and analysis.

B. Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov.* Insert the docket number, FMCSA–2014–0470, in the keyword box, and click "Search." Next, click the "Open Docket Folder" button and choose the document to review. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

C. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

II. Legal Basis for the Rulemaking

Section 32710 of Motorcoach Enhanced Safety Act of 2012, enacted as part of MAP–21, requires that the Secretary of Transportation complete a rulemaking proceeding to consider requiring States to establish a program for annual inspections of vehicles designed or used to transport passengers (Pub. L. 112–141). As part of this proceeding, FMCSA must assess: (1) The risks associated with improperly maintained or inspected CMVs designed or used to transport passengers; (2) the effectiveness of existing Federal inspection standards in mitigating the risks associated with improperly maintained vehicles and ensuring safe and proper operation; and (3) the costs and benefits of a mandatory inspection program.

III. Background

Section 210 of the Motor Carrier Safety Act of 1984 required the Secretary of Transportation to prescribe standards for the inspection of CMVs. *See* 49 U.S.C. 31142. Under the Federal Motor Carrier Safety Regulations (FMCSR), a CMV, including qualifying passenger vehicles,[1] must be inspected at least once every 12 months. *See* 49 CFR 396.17. Subject to exceptions under § 396.23, a motor carrier must either conduct the inspection using its own qualified personnel or use a qualified third party that maintains appropriate facilities and employs inspectors qualified under § 396.19. In lieu of conducting a self-inspection or relying on a third-party inspector under § 396.17, a motor carrier may satisfy the FMCSR annual inspection requirement through a State or other jurisdiction's inspection program in accordance with § 396.23(a), provided that the inspection satisfies regulatory requirements.

However, in those States that have a mandatory State inspection requirement that the FMCSA Administrator has determined to be as effective as inspections under § 396.17, a motor carrier may rely on the State inspection process in order to satisfy the annual inspection requirement. 49 CFR 396.23(b)(1). A State inspection under this provision might be conducted by State personnel, at a State-authorized commercial facility, or by the motor carrier under the auspices of a State-authorized self-inspection program. *Id.* According to the latest list published by FMCSA, 22 States are among the governmental entities that have mandatory inspections programs recognized by the FMCSA Administrator. 73 FR 63040 (October 22, 2008).[2]

In 2012, Congress enacted legislation requiring the Secretary of Transportation to complete a rulemaking proceeding to consider requiring States to establish an annual inspection program as discussed under the Legal Basis section, above. Subsequently, FMCSA conducted three public listening sessions that provided interested parties with the opportunity to share their views on the merits of requiring State inspections of passenger CMVs.[3] Transcripts of these sessions are available in the public docket noted above. Stakeholders' presentations proved valuable in developing the questions posed in today's ANPRM. While the Agency received a broad range of comments, recurring themes included the costs of mandatory inspection programs, the value of a nation-wide uniform inspection standard, and the need for national training of inspectors to eliminate inconsistencies in how inspection standards are applied. Both industry and the enforcement community identified concerns about the cost of the inspection programs. Stakeholders' estimates of costs for program administration and individual inspections varied significantly. Industry stakeholders expressed concern about inconsistent inspections under existing programs.

Section 32710 of MAP–21 did not address the Agency's authority to require mandatory State inspection programs. While Congress has granted the Secretary broad regulatory authority over the interstate operation of CMVs, under Federalism principles and the 10th Amendment, the Federal government may not compel the States to enact or administer a Federal regulatory program (*New York* v. *United States,* 505 U.S. 144, 188 (1992)), or compel State officers to administer or enforce a Federal regulatory program (*Printz* v. *United States,* 521 U.S. 898, 935 (1997)). Thus, FMCSA assumes Congress intended that State participation would be required as a condition of receiving Federal funds. *See, e.g., South Dakota* v. *Dole,* 483 U.S. 203, 206–207 (1987). However, Congress neither established a new financial assistance program for funding State inspection programs nor specified what existing financial assistance program FMCSA might employ to incentivize States to adopt inspection programs. Thus, in posing its final question below, the Agency is seeking its State partners' views on how to implement and incentivize a required State inspection program, should the Agency propose such a program.

IV. Questions

FMCSA is considering a rulemaking under which States would establish a program for annual inspections of CMVs designed or used to transport passengers. The Agency will use information gathered through this ANPRM to quantify the economic benefits and costs of this action if it issues an NPRM. The Agency encourages parties with knowledge of the industry to provide information about the impact that such a rule would have on current regulations, operating costs, business practices, safety, and any other areas that would be affected by a rule requiring States to establish inspection programs.

FMCSA also requests responses to the following issues and questions. Again, whenever possible, commenters should provide data. FMCSA also encourages stakeholders to describe any applicable regulatory inspection process under which they operate. FMCSA recognizes that an individual commenter may choose to respond to all of the issues or only a subset, based on his or her interest or area of expertise.

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[1] A CMV is defined, in part, for purposes of this regulation as a "motor vehicle used on a highway in interstate commerce to transport passengers . . . when the vehicle—(1) [h]as a gross vehicle weight rating or gross combination weight rating, or gross vehicle weight or gross combination weight, of 4,536 kg (10,001 pounds) or more, whichever is greater; or (2) [i]s designed or used to transport more than 8 passengers (including the driver) for compensation; or (3) [i]s designed or used to transport more than 15 passengers, including the driver, and is not used to transport passengers for compensation . . ." 49 CFR 390.5.

[2] At the time of publication, the list of State inspection programs determined comparable to, or as effective as, the FMCSA periodic inspection program included California, Connecticut, Hawaii, Illinois, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, Texas, Utah, Vermont, Virginia, West Virginia, and Wisconsin. Other jurisdictions and agencies with approved programs are the District of Columbia, the Alabama LPG Board, the 10 Canadian Provinces, and the Yukon Territory. However FMCSA does not collect inspection data on passenger CMVs that are not subject to FMCSAs regulatory authority.

[3] The listening sessions were conducted at the American Bus Association Marketplace in St. Louis, Missouri on January 13, 2015, a United Motor Coach Association meeting in New Orleans, Louisiana on January 18, 2015, and a Commercial Vehicle Safety Alliance workshop in Jacksonville, Florida on April 14, 2015.

Existing State Mandatory Vehicle Inspection Programs for Passenger-Carrying Commercial Motor Vehicles (CMVs)

1. Does your State or the States in which you register your passenger-carrying CMV conduct mandatory inspections of such vehicles? Please indicate the State(s) in which your passenger-carrying CMVs are registered.

2. What vehicle types are included in the mandatory passenger-carrying CMV inspection program (*e.g.,* motorcoaches, school buses, mini-buses, 9–15 passenger vans, etc.) and which are not included?

3. If your State has a mandatory program, briefly describe your inspection procedures and indicate which vehicle components are inspected.

4. How many total inspections are performed by your State annually for each of the following types of vehicles?

a. Motorcoaches
b. School buses
c. Mini-buses
d. 9–15 passenger vans
e. Other

5. What is the estimated time required to complete each vehicle inspection?

6. What procedures are used to record the vehicle inspection?

7. If a vehicle does not pass an inspection, who addresses the issues? If it is done by someone other than the inspecting entity, is there a second inspection after the issues are addressed? On average, how many follow up inspections does it take to pass a vehicle?

8. Are mandatory vehicle inspections performed by State employees, by third-party inspectors authorized by the State, or by passenger carrier employees through a State-authorized self-inspection program?

9. If vehicle inspections are conducted by a State-authorized third party or by passenger-carrier employees authorized by the State, are there differences in safety outcomes between those conducted by State employees and those conducted by third-party inspectors or through a passenger carrier's State-authorized self-inspection facilities?

10. Are there any specific benefits or concerns related to using third-party inspectors or by others?

11. If inspections are conducted by third-party inspectors or by passenger carrier-employed mechanics or technicians, what oversight is or should be required?

12. Should self-inspection or third-party inspections be options for compliance with a mandatory State inspection?

13. How does/would the cost of inspections differ between those conducted by State employees or by third-party inspectors?

14. What might be other preferable options?

Measuring Effectiveness of Inspection Programs

15. Does your State have information on violations discovered during inspections that are attributable to maintenance issues that should have been found during a required vehicle inspection?

16. Has your State considered implementing a mandatory passenger-carrying CMV inspection program, but declined to do so? If so, what are your State's reasons for not implementing a program?

17. If your State imposes mandatory inspection of passenger-carrying CMVs, how is the effectiveness of that program measured?

18. What are the most common vehicle defects discovered during these mandatory vehicle inspections? What safety conclusions do you draw from the results of these inspections?

19. Has your State or organization collected data related to crashes, injuries, or fatalities attributable to improperly maintained or inspected passenger-carrying CMVs? If so, please provide summary information or links to detailed data associated with these areas.

20. Has the occurrence of passenger-carrying CMV-involved crashes, injuries, or fatalities before and after the implementation of a mandatory inspection requirement been evaluated? If so, please provide summary information or links to detailed data associated with these areas.

21. After a State inspection requirement was instituted, what changes were observed over time in the number of safety violations discovered during inspections, if any.

22. Do programs that inspect only a sample of vehicles have significantly different outcomes than those where all vehicles are inspected, please provide examples of how they differ?

Inspection Facilities and Locations

23. Where does your State conduct mandatory passenger-carrying CMV inspections (*e.g.,* State owned/leased facility, third party facility, carrier's place of business, or other type of facility)?

24. Where should mandatory passenger-carrying CMV inspections be performed?

25. If mandatory passenger-carrying CMV inspections are conducted at the carrier's place of business, what accommodations must be made to ensure appropriate access (*e.g.,* pits, lifts, etc.) to conduct full inspections of motorcoaches and other large passenger vehicles?

26. How does facility location or accessibility for mandatory inspections impact inspections or compliance?

27. What delays may the State experience in completing mandatory inspections (*e.g.* lack of sufficient number of inspection facilities)?

Costs

28. What is the cost per mandatory vehicle inspection to the carrier?

29. Do inspection fees differ based on the type of vehicle being inspected?

30. Do vehicle inspection fees differ based on location of the inspections?

31. How much does it cost the State to establish and run inspection programs on an annual basis?

32. If a vehicle does not pass an inspection, is there an additional cost for the second inspection?

33. If fees are collected by the State, does the State dedicate the revenue to the administration of the program?

Uniformity of Mandatory Vehicle Inspection Programs

34. What qualifications should be applicable to individuals authorized to perform mandatory passenger-carrying CMV inspections?

35. Should minimum training elements be required for passenger-carrying CMV inspections? If so, how much training should be required and who should administer the training?

36. What should be the minimum vehicle components inspected under a mandatory bus inspection program?

37. How does the existence of different vehicle inspection requirements among the States affect carrier business practices?

38. How might business practices change under a uniform mandatory bus inspection program?

Current Federal Standards

39. How effective are existing Federal standards for the inspection of passenger-carrying CMVs in (1) mitigating the risks associated with improperly maintained vehicles and (2) ensuring the safe and proper operating condition of the vehicles?

40. What is an effective and efficient way for the FMCSA to track inspected carriers to reduce burden on States and carriers?

Federal Authority

41. How should FMCSA incentivize the States to establish mandatory

passenger-carrying CMV inspection programs?

Issued under the authority of delegation in 49 CFR 1.87 on April 20, 2016.

T.F. Scott Darling, III,

Acting Administrator.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[Docket No. 160205084–6084–01]

RIN 0648–BF76

International Fisheries; Western and Central Pacific Fisheries for Highly Migratory Species; Purse Seine Observer Requirements, and Fishing Restrictions and Limits in Purse Seine and Longline Fisheries for 2016–2017

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS seeks comments on this proposed rule issued under authority of the Western and Central Pacific Fisheries Convention Implementation Act (WCPFC Implementation Act). The proposed rule would, first, require that U.S. purse seine vessels carry observers on fishing trips in the western and central Pacific Ocean (WCPO); second, establish restrictions in 2016 and 2017 on the use of fish aggregating devices (FADs) by U.S. purse seine vessels in the WCPO; and third, establish limits in 2016 and 2017 on the amount of bigeye tuna that may be captured by U.S. longline vessels in the WCPO. This action is necessary to satisfy the obligations of the United States under the Convention on the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean (Convention), to which it is a Contracting Party.

DATES: Comments on the proposed rule must be submitted in writing by May 12, 2016.

ADDRESSES: You may submit comments on the proposed rule and the regulatory impact review (RIR) prepared for the proposed rule, identified by NOAA–NMFS–2016–0031, by either of the following methods:

- *Electronic submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal.

1. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2016-0031,*
2. Click the "Comment Now!" icon, complete the required fields, and
3. Enter or attach your comments.

—OR—

- *Mail:* Submit written comments to Michael D. Tosatto, Regional Administrator, NMFS, Pacific Islands Regional Office (PIRO), 1845 Wasp Blvd., Building 176, Honolulu, HI 96818.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, might not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name and address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter "N/A" in the required fields if you wish to remain anonymous).

An initial regulatory flexibility analysis (IRFA) prepared under authority of the Regulatory Flexibility Act is included in the Classification section of the **SUPPLEMENTARY INFORMATION** section of this document.

Copies of the RIR and the programmatic environmental assessment (PEA) prepared for National Environmental Policy Act (NEPA) purposes are available at *www.regulations.gov* or may be obtained from Michael D. Tosatto, Regional Administrator, NMFS PIRO (see address above).

FOR FURTHER INFORMATION CONTACT: Tom Graham, NMFS PIRO, 808–725–5032.

SUPPLEMENTARY INFORMATION:

Background on the Convention

The Convention focuses on the conservation and management of fisheries for highly migratory species (HMS). The objective of the Convention is to ensure, through effective management, the long-term conservation and sustainable use of HMS in the WCPO. To accomplish this objective, the Convention established the Commission for the Conservation and Management of Highly Migratory Fish Stocks in the Western and Central Pacific Ocean (Commission or WCPFC), which includes Members, Cooperating Non-members, and Participating Territories (collectively referred to here as "members"). The United States of America is a Member. American Samoa, Guam, and the Commonwealth of the Northern Mariana Islands (CNMI) are Participating Territories.

As a Contracting Party to the Convention and a Member of the Commission, the United States implements conservation and management measures and other decisions adopted by the Commission. The WCPFC Implementation Act (16 U.S.C. 6901 *et seq.*), authorizes the Secretary of Commerce, in consultation with the Secretary of State and the Secretary of the Department in which the United States Coast Guard is operating (currently the Department of Homeland Security), to promulgate such regulations as may be necessary to carry out the obligations of the United States under the Convention, including the decisions of the Commission. The WCPFC Implementation Act further provides that the Secretary of Commerce shall ensure consistency, to the extent practicable, of fishery management programs administered under the WCPFC Implementation Act and the Magnuson-Stevens Fishery Conservation and Management Act (MSA; 16 U.S.C. 1801 *et seq.*), as well as other specific laws (see 16 U.S.C. 6905(b)). The Secretary of Commerce has delegated the authority to promulgate regulations under the WCPFC Implementation Act to NMFS. A map showing the boundaries of the area of application of the Convention (Convention Area), which comprises the majority of the WCPO, can be found on the WCPFC Web site at: *www.wcpfc.int/doc/convention-area-map.*

Proposed Action

This proposed rule includes three elements, described in detail below, that would be included in regulations at 50 CFR part 300, subpart O. The three elements would implement specific provisions of the Commission's Conservation and Management Measure (CMM) 2015–01, "Conservation and Management Measure for Bigeye, Yellowfin, and Skipjack Tuna in the Western and Central Pacific Ocean." CMM 2015–01 was adopted by the Commission at its twelth regular annual session, in December 2015, went into effect February 6, 2016, and is generally applicable for the 2016–2017 period. CMM 2015–01 is the latest in a series of CMMs devoted to the conservation and management of tropical tuna stocks, particularly stocks of bigeye tuna (*Thunnus obesus*), yellowfin tuna (*Thunnus albacares*), and skipjack tuna (*Katsuwonus pelamis*). CMM 2015–01 maintains the provisions of its predecessor, CMM 2014–01. The stated objective of CMM 2015–01 and several of its predecessor CMMs is to ensure that the stocks of bigeye tuna, yellowfin tuna, and skipjack tuna in the WCPO are, at a minimum, maintained at levels capable of producing their maximum sustainable yield as qualified by relevant environmental and economic factors. The CMM includes specific objectives for each of the three stocks: For each, the fishing mortality rate is to be reduced to or maintained at levels no greater than the fishing mortality rate associated with maximum sustainable yield.

1. Purse Seine Observer Requirements

CMM 2015–01 requires that each member of the Commission ensure that any of its flagged purse seine vessels fishing in the Convention Area between the latitudes of 20° N. and 20° S.—with the exception of fishing exclusively in waters under the jurisdiction of a single nation—carry a WCPFC observer. Additionally, CMM 2015–01 requires that each member of the Commission ensure that any purse seine vessel fishing exclusively in that member's waters in the Convention Area between the latitudes of 20° N. and 20° S. carry an observer (not necessarily a WCPFC observer). A WCPFC observer is an observer deployed from an observer program that has been authorized by the Commission to be part of the WCPFC Regional Observer Programme (see 50 CFR 300.211).

NMFS proposes to satisfy these provisions of CMM 2015–01 by prohibiting U.S. purse seine vessels from fishing in the Convention Area between the latitudes of 20° N. and 20° S. without a WCPFC observer on board, with the exception of fishing trips during which any fishing in the Convention Area takes place entirely within areas under the jurisdiction of a single nation other than the United States. Although U.S. purse seine vessels would be exempt from this requirement on trips in which fishing occurs only in the waters of a single foreign nation, it is expected that such foreign nations would require that U.S. purse seine vessels carry observers if fishing in their waters.

Currently, the Pacific Islands Forum Fisheries Agency (FFA) observer program, from which observers for the U.S. WCPO purse seine fleet have traditionally been deployed, and the NMFS observer program, among others, are authorized as part of the WCPFC Regional Observer Programme. Thus, observers deployed by these programs are considered WCPFC observers.

The Commission has had purse seine observer requirements similar to those in CMM 2015–01 since 2008, when it adopted CMM 2008–01. In recent years, NMFS has been implementing those requirements through the regulation at 50 CFR 300.215(c), which authorizes NMFS to direct owners and operators of fishing vessels to carry WCPFC observers on fishing trips during which the vessel at any time enters or is within the Convention Area. NMFS has been issuing directives annually, by letter to the owners of affected purse seine vessels. To help ensure that all affected parties have effective notice of the requirement, NMFS proposes here to establish specific observer requirements for purse seine vessels in the regulations, rather than by letter directives issued under 50 CFR 300.215(c).

2. Purse Seine FAD Restrictions for 2016–2017

Paragraphs 14–19 of CMM 2015–01 require WCPFC members to implement certain restrictions on the use of FADs by purse seine fishing vessels. All the restrictions are to be applied in the Convention Area between the latitudes of 20° N. and 20° S.

Under paragraph 14, Commission members are to prohibit their purse seine vessels from setting on FADs during the three-month period July through September in each of 2016 and 2017. Under paragraphs 15–18, members have the option of applying either: (1) Two additional FAD closure months (January and February in addition to July through September), or (2) in addition to the three-month FAD closure referenced in paragraph 14, limiting the total number of FAD sets by its vessels to the number listed in Column B of Attachment A of CMM 2015–01 (*i.e.,* for the United States, 2,202 sets for each of 2015 and 2016).

Importantly, however, under paragraph 15, the provisions regarding a fifth FAD closure month and the annual FAD set limits identified in paragraph 17 do not take effect until the Commission adopts arrangements to ensure that the action does not result in transferring, directly or indirectly, a disproportionate burden of conservation action onto small island developing states. The Commission has not yet adopted such arrangements. Until these decisions are taken, NMFS construes the obligations of the United States under paragraphs 15–18 to require either adding a fourth month, October, to the July-September FAD prohibition period in each of 2016 and 2017, or alternatively, limiting the number of FAD sets in each of those two years to 2,522 (from Column A of Attachment A of CMM 2015–01).

Finally, under paragraph 18, Commission members are to prohibit setting on FADs on the high seas in the Convention Area in 2017.

In accordance with paragraph 14 of the CMM, NMFS proposes to establish a FAD prohibition period from July through September in each of 2016 and 2017. Regarding the choice between an additional month of closure in October each year and a limit of 2,522 FAD sets each year, the Commission designed the CMM such that the two options were roughly equivalent in terms of their expected effects on the fishing mortality of bigeye tuna. The Commission provides no guidance to inform the selection of either option, which is left to the discretion of individual Commission members. After considering the objectives of CMM 2015–01, the expected economic impacts on U.S. fishing operations and the nation as a whole, and expected environmental and other effects, NMFS expects that for both 2016 and 2017, a limit of 2,522 FAD sets is likely to be somewhat more cost-effective than a FAD prohibition period in October. For this reason, NMFS is proposing to implement this option for 2016 and 2017. We specifically seek public comment on which option is more appropriate. A comparison of the two options' expected economic impacts on affected fishing businesses is provided in the IRFA.

Finally, this proposed rule would establish specific measures that NMFS deems necessary to implement the prohibition on FAD sets on the high seas for 2017, in accordance with paragraph 18 of CMM 2015–01. As currently defined in 50 CFR 300.211, a FAD is "any artificial or natural floating object, whether anchored or not and whether situated at the water surface or not, that is capable of aggregating fish, as well as any object used for that purpose that is situated on board a vessel or otherwise out of the water. The definition of FAD does not include a vessel." Under this proposed rule, the regulatory definition of a FAD would not change. Although the definition of a FAD does not include a vessel, the restrictions during the FAD prohibition periods would include certain activities related to fish that have aggregated in association with a vessel, or drawn by a vessel, as described below.

In summary, this proposed rule would establish: FAD prohibition periods from July 1 through September 30 in each of 2016 and 2017; a limit of 2,522 FAD sets that may be made in each of 2016 and 2017; and specific measures that are necessary to implement the United States' obligation to prohibit its purse seine vessels from setting on FADs on the high seas throughout 2017. The prohibitions applicable to these proposed FAD-related measures are in existing regulations at 50 CFR 300.223(b)(1)(i)–(v). Specifically, during the July–September FAD prohibition periods in each of 2016 and 2017, after the 2,522 FAD set limit is reached in either 2016 or 2017 (until the end of the respective calendar year), and on the high seas throughout 2017, owners, operators, and crew of fishing vessels of the United States would be prohibited from doing any of the following activities in the Convention Area in the area between 20° N. latitude and 20° S. latitude:

(1) Set a purse seine around a FAD or within one nautical mile of a FAD.

(2) Set a purse seine in a manner intended to capture fish that have aggregated in association with a FAD or a vessel, such as by setting the purse seine in an area from which a FAD or a vessel has been moved or removed within the previous eight hours, setting the purse seine in an area in which a FAD has been inspected or handled within the previous eight hours, or setting the purse seine in an area into which fish were drawn by a vessel from the vicinity of a FAD or a vessel.

(3) Deploy a FAD into the water.

(4) Repair, clean, maintain, or otherwise service a FAD, including any electronic equipment used in association with a FAD, in the water or on a vessel while at sea, except that: a FAD may be inspected and handled as needed to identify the FAD, identify and release incidentally captured animals, un-foul fishing gear, or prevent damage to property or risk to human safety; and a FAD may be removed from the water and if removed may be cleaned, provided that it is not returned to the water.

(5) From a purse seine vessel or any associated skiffs, other watercraft or equipment, submerge lights under water; suspend or hang lights over the side of the purse seine vessel, skiff, watercraft or equipment, or direct or use lights in a manner other than as needed to illuminate the deck of the purse seine vessel or associated skiffs, watercraft or equipment, to comply with navigational requirements, and to ensure the health and safety of the crew. These prohibitions would not apply during emergencies as needed to prevent human injury or the loss of human life, the loss of the purse seine vessel, skiffs, watercraft or aircraft, or environmental damage.

3. Longline Bigeye Tuna Catch Limits for 2016–2017

Under paragraphs 40–42 CMM 2015–01, Commission members are to limit catches by their longline vessels of bigeye tuna in the Convention Area to specified levels in each of 2016 and 2017. The applicable limits for the United States in 2016 and 2017 are 3,554 metric tons (mt) and 3,345 mt, respectively. In addition, paragraph 40 of the CMM states that any catch overage in a given year shall be deducted from the catch limit for the following year. This provision was also in CMM 2014–01, the predecessor to CMM 2015–01, so it pertains to the catch limit for 2016 as well as 2017. The Commission has not adopted limits for the longline fisheries of any of the U.S. Participating Territories, American Samoa, Guam, and the CNMI.

As stated above, the Commission-adopted limit for 2016 is 3,554 mt less any overage of the limit applicable in 2015. The limit for 2015 was 3,502 mt (see the final rule that established the 2015 limit at 80 FR 43634; published July 23, 2015). NMFS has not yet made the final estimate of bigeye tuna catches in 2015 with respect to the 2015 limit. NMFS anticipates being able to do so sometime in April of 2016. Because that estimate is not yet available, NMFS proposes here a limit for 2016 set at 3,554 mt, which assumes there was no overage in 2015. If NMFS later determines that there was an overage in 2015, NMFS would adjust the 2016 limit as follows: an amount equal to that overage will be subtracted from 3,554 mt to determine the annual limit for 2016. NMFS also proposes here a limit for 2017 set at 3,345 mt, which similarly assumes that there will be no overage of the 2016 limit. If NMFS, when it makes its final estimate of the 2016 catch in early 2017, determines that an overage has occurred, it would revise the 2017 limit accordingly.

These proposed limits for 2016 and 2017 would be applied in the manner set out in existing regulations at 50 CFR 300.224(b)–(f), which would not be revised by this proposed rule. Following is a description of the application of these existing regulations, subject to the proposed limits for 2016 and 2017.

The 2016 and 2017 longline bigeye tuna catch limits would apply only to U.S-flagged longline vessels operating as part of the U.S. longline fisheries. The limits would not apply to U.S. longline vessels operating as part of the longline fisheries of American Samoa, the CNMI, or Guam. Existing regulations at 50 CFR 300.224(b), (c), and (d) detail the manner in which longline-caught bigeye tuna is attributed among the fisheries of the United States and the U.S. Participating Territories.

Consistent with the basis for the limits prescribed in CMM 2015–01 and with previous rules issued by NMFS to implement bigeye tuna catch limits in U.S. longline fisheries, the catch limits would be measured in terms of retained catches—that is, bigeye tuna that are caught by longline gear and retained on board the vessel.

As set forth under the existing regulations at 50 CFR 300.224(e), if NMFS determines that the 2016 or 2017 limit is expected to be reached before the end of the respective calendar year, NMFS would publish a notice in the **Federal Register** to announce specific fishing restrictions that would be effective from the date the limit is expected to be reached until the end of that calendar year. NMFS would publish the notice of the restrictions at least 7 calendar days before the effective date to provide vessel owners and operators with advance notice. Periodic forecasts of the date the limit is expected to be reached would be made available to the public on the Web site of the NMFS Pacific Islands Regional Office, at *www.fpir.noaa.gov/SFD/SFD_regs_3.html,* to help vessel owners and operators plan for the possibility of the limit being reached.

As set forth under the existing regulations at 50 CFR 300.224(f), if the 2016 or 2017 limit is reached, the following restrictions would go into effect:

(1) Retaining on board, transshipping, or landing bigeye tuna: Starting on the effective date of the restrictions and extending through December 31 of the applicable year, it would be prohibited to use a U.S. fishing vessel to retain on board, transship, or land bigeye tuna captured in the Convention Area by longline gear, with three exceptions, as described below.

First, any bigeye tuna already on board a fishing vessel upon the effective date of the restrictions may be retained on board, transshipped, and/or landed, provided that they are landed within 14 days after the restrictions become effective. A vessel that had declared to NMFS pursuant to 50 CFR 665.803(a) that the current trip type is shallow-setting would not be subject to this 14-day landing restriction, so these vessels would be able to land bigeye tuna more than 14 days after the restrictions become effective.

Second, bigeye tuna captured by longline gear may be retained on board, transshipped, and/or landed if they are caught by a fishing vessel registered for use under a valid American Samoa

Longline Limited Access Permit, or if they are landed in American Samoa, Guam, or the CNMI. However, the bigeye tuna must not be caught in the portion of the U.S. EEZ surrounding the Hawaiian Archipelago, and must be landed by a U.S. fishing vessel operated in compliance with a valid permit issued under 50 CFR 660.707 or 665.801.

Third, bigeye tuna captured by longline gear may be retained on board, transshipped, and/or landed if they are caught by a vessel that is included in a valid specified fishing agreement under 50 CFR 665.819(d), in accordance with 50 CFR 300.224(f)(1)(iv).

(2) Transshipping bigeye tuna to certain vessels: To the extent authorized under the prohibition described above on "retaining on board, transshipping, or landing bigeye tuna," starting on the effective date of the restrictions and extending through December 31 of the applicable year, it would be prohibited to transship bigeye tuna caught by longline gear in the Convention Area to any vessel other than a U.S. fishing vessel operated in compliance with a valid permit issued under 50 CFR 660.707 or 665.801.

(3) Fishing inside and outside the Convention Area: To help ensure compliance with the restrictions related to bigeye tuna caught by longline gear in the Convention Area, the proposed rule would establish two additional, related prohibitions that would go into effect starting on the effective date of the restrictions and extending through December 31 of the applicable year. First, vessels would be prohibited from fishing with longline gear both inside and outside the Convention Area during the same fishing trip, with the exception of a fishing trip that is in progress at the time the announced restrictions go into effect. In the case of a fishing trip that is in progress at the time the restrictions go into effect, the vessel still must land any bigeye tuna taken in the Convention Area within 14 days of the effective date of the restrictions, as described above. Second, if a vessel is used to fish using longline gear outside the Convention Area and enters the Convention Area at any time during the same fishing trip, the longline gear on the fishing vessel must be stowed in a manner so as not to be readily available for fishing while the vessel is in the Convention Area. These two prohibitions would not apply to vessels on declared shallow-setting trips pursuant to 50 CFR 665.803(a), or vessels operating for the purposes of this rule as part of the longline fisheries of American Samoa, Guam, or the CNMI. This second group includes vessels registered for use under valid American Samoa Longline Limited Access Permits; vessels landing their bigeye tuna catch in one of the three U.S. Participating Territories, so long as these vessels conduct fishing activities in accordance with the conditions described above; and vessels included in a specified fishing agreement under 50 CFR 665.819(d), in accordance with 50 CFR 300.224(f)(1)(iv).

Classification

The Administrator, Pacific Islands Region, NMFS, has determined that this proposed rule is consistent with the WCPFC Implementation Act and other applicable laws, subject to further consideration after public comment.

Executive Order 12866

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

Regulatory Flexibility Act (RFA)

An initial regulatory flexibility analysis (IRFA) was prepared, as required by section 603 of the RFA. The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities. A description of the action, why it is being considered, and the legal basis for this action are contained in the **SUMMARY** section of the preamble and in other sections of this **SUPPLEMENTARY INFORMATION** section of the preamble. The analysis follows:

Estimated Number of Small Entities Affected

Small entities include "small businesses," "small organizations," and "small governmental jurisdictions." The Small Business Administration (SBA) has established size standards for all major industry sectors in the United States, including commercial finfish harvesters (NAICS code 114111). A business primarily involved in finfish harvesting is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $20.5 million for all its affiliated operations worldwide.

The proposed rule would apply to owners and operators of U.S. purse seine and longline vessels used for fishing for HMS in the Convention Area. The number of purse seine vessels that would be affected by the rule is approximated by the number with WCPFC Area Endorsements, which are the NMFS-issued authorizations required to use a vessel to fish commercially for HMS on the high seas in the Convention Area. As of March 2016 the number of purse seine vessels with WCPFC Area Endorsements was 41.

The proposed rule would apply to U.S. longline vessels used to fish for HMS in the Convention Area, except those operating as part of the longline fisheries of American Samoa, the CNMI, or Guam. The total number of affected longline vessels is approximated by the number of vessels with Hawaii Longline Limited Access Permits (issued under 50 CFR 665.13), although some such vessels might be able to operate as part of the longline fisheries of the U.S. Participating Territories and thus not be affected. Under the Hawaii longline limited access program, no more than 164 permits may be issued. During 2006–2012 the number of permitted vessels ranged from 130 to 145. The current number of permitted vessels (as of March 2016) is 113, but NMFS expects the number to increase to more typical historical levels soon, as vessel owners renew their permits, which expire in March each year. U.S. longline vessels based on the U.S. west coast without Hawaii Longline Limited Access Permits also could be affected by this proposed rule if they fish in the Convention Area. However, the number of such vessels is very small and fishing in the Convention Area by such vessels is rare, so it is expected that very few, if any, such vessels would be affected.

Most of the Hawaii longline fleet targets bigeye tuna using deep sets, and during certain parts of the year, portions of the fleet target swordfish using shallow sets. In the years 2005 through 2012, the estimated numbers of Hawaii longline vessels that actually fished ranged from 124 to 129. Of the vessels that fished, the number of vessels that engaged in deep-setting in the years 2005 through 2012 ranged from 122 to 129, and the number of vessels that engaged in shallow-setting ranged from 18 to 35. The number of vessels that engaged in both deep-setting and shallow-setting ranged from 17 to 35. The number of vessels that engaged exclusively in shallow-setting ranged from zero to two.

Based on limited available financial information about the affected fishing vessels and the SBA's small entity size standards for commercial finfish harvesters, and using individual vessels as proxies for individual businesses, NMFS believes that all the affected fish harvesting businesses—in both the purse seine and longline sectors—are small entities. NMFS used average per-vessel returns over recent years to estimate annual revenue, because gross receipts and ex-vessel price information specific to the individual affected vessels are not available to NMFS.

For the affected purse seine vessels, 2013 is the most recent year for which complete catch data are available, and NMFS estimates that the average annual receipts over 2011–2013 for each purse seine vessel were less than the $20.5 million threshold for finfish harvesting businesses. The greatest was about $20 million, and the average was about $12 million. This is based on the estimated catches of each vessel in the purse seine fleet during that period, and indicative regional cannery prices developed by the FFA (available at *https://www.ffa.int/node/425*). Since 2013, cannery prices for purse seine-caught tuna have declined dramatically, so the vessels' revenues in 2014 and 2015 very likely declined as well.

For the longline fishery, the ex-vessel value of catches by the Hawaii longline fleet in 2012 was about $87 million. With 129 active vessels in that year, per-vessel average revenues were about $0.7 million, well below the $20.5 million threshold for finfish harvesting businesses.

Recordkeeping, Reporting, and Other Compliance Requirements

The recordkeeping, reporting, and other compliance requirements are discussed below for the proposed purse seine observer requirements, as described earlier in the **SUPPLEMENTARY INFORMATION** section of the preamble. Fulfillment of these requirements is not expected to require any professional skills that the affected vessel owners and operators do not already possess. The costs of complying with the proposed requirements are described below to the extent possible:

1. Purse Seine Observer Requirements

This element of the proposed rule would not establish any new reporting or recordkeeping requirements. The new compliance requirement would be for affected vessel owners and operators to carry WCPFC observers on all fishing trips in the Convention Area between the latitudes of 20° N. and 20° S., with the exception of fishing trips during which any fishing in the Convention Area takes place entirely within areas under the jurisdiction of a single nation other than the United States.

Fulfillment of this requirement is not expected to require any professional skills that the vessel owners and operators do not already possess. The expected costs of complying with this requirement are described below.

Under the South Pacific Tuna Treaty (SPTT), U.S. purse seine vessels operating in the Treaty Area (which is almost entirely in the Convention Area) are required to carry observers on about 20 percent of their fishing trips, which equates to roughly one trip per year per vessel. The observers required under the terms of the SPTT are deployed by the FFA, which acts as the SPTT Administrator on behalf of the Pacific Island Parties to the SPTT. The FFA observer program has been authorized to be part of the WCPFC observer program, so FFA-deployed observers are also WCPFC observers. Thus, in a typical year for a typical U.S. purse seine vessel, the cost of carrying observers to satisfy requirements under the SPTT can be expected to constitute 20 percent of the costs of the proposed requirement considered here. However, recent events associated with the SPTT make 2016 an atypical year. Because of late negotiations among the SPTT parties on the terms of access in foreign zones in the SPTT Area for 2016, no U.S. vessels were licensed under the SPTT until March of 2016, and thus none were authorized to fish in foreign zones or on the high seas in the Treaty Area until then. The terms of access for future years, and the SPTT itself, are uncertain. Given this uncertainty, an upper-bound estimate of the costs of compliance is provided here. For this purpose, it is assumed that fishing patterns in the Convention Area will be similar to the pattern in recent years, and that observer coverage under the terms of the SPTT will not contribute at all to the costs of complying with this proposed requirement.

Based on the U.S. purse seine fleet's fishing patterns in 2011–2013, it is expected that each vessel will spend about 252 days at sea per year, on average, with some vessels spending as many as about 354 days at sea per year.

The compliance costs of the proposed requirement can be broken into two parts: (1) The costs of providing food, accommodation, and medical facilities to observers (observer accommodation costs); and (2) the fees imposed by observer providers for deploying observers (observer deployment costs). Observer accommodation costs are expected to be about $20 per vessel per day-at-sea.

With respect to observer deployment costs, affected fishing companies could use observers from any program that has been authorized by the Commission to be part of the WCPFC Regional Observer Programme. In other words, they would not be required to use FFA observers, which they have traditionally used until now. Nonetheless, the costs of deploying FFA observers are probably good indications of observer deployment costs in the region generally, and they are used for this analysis. Based on budgets and arrangements for the deployment of observers under the FFA observer program, observer deployment costs are expected to be about $230 per vessel per day-at-sea. Thus, combined observer accommodation costs and observer deployment costs are expected to be about $250 per vessel per day-at-sea. For the average vessel, which is expected to spend about 252 days at sea per year, the total cost of compliance would therefore be about $63,000 per year. The cost for vessels that spend fewer days at sea would be accordingly less. At the other extreme, if a vessel spends 354 days at sea (the top of the range in 2011–2013), the total cost of compliance would be about $88,500 per year. Both of these figures are upper-bound estimates. If arrangements under the SPTT return to something like they have been in the past, then the numbers of days spent at sea on fishing trips in the Convention Area are likely be close to the levels described above, but the compliance costs would be about 20 percent less than estimated above because observer coverage under the SPTT would satisfy about 20 percent of the coverage required under this rule. If arrangements under the SPTT do not return to something like they have been in the recent past, then the number of days spent at sea on fishing trips in the Convention Area could be substantially lower than as described above, and the costs of complying with this proposed requirement would be accordingly less.

2. Purse Seine FAD Restrictions for 2016–2017

This element of the proposed rule would not establish any new reporting or recordkeeping requirements. The new requirement would be for affected vessel owners and operators to comply with the FAD restrictions described earlier in the **SUPPLEMENTARY INFORMATION** section of the preamble, including FAD prohibition periods from July 1 through September 30 in each of 2016 and 2017; limits of 2,522 FAD sets that may be made in each of 2016 and 2017; and prohibitions on specific uses of FADs on the high seas in 2017.

Compliance with these restrictions is not expected to require any professional skills that the vessel owners and operators do not already possess. The expected costs of complying with this requirement are described below to the extent possible.

The proposed FAD restrictions would substantially constrain the manner in which purse seine fishing could be conducted in the specified areas and periods in the Convention Area; in those areas and during those periods, vessels would be able to set only on free, or "unassociated," schools.

The costs associated with the proposed FAD restrictions cannot be quantitatively estimated, but the fleet's historical use of FADs can give a qualitative indication of the costs. In the years 1997–2013, the proportion of sets made on FADs in the U.S. purse seine fishery ranged from less than 30 percent in some years to more than 90 percent in others. Thus, the importance of FAD sets in terms of profits appears to be quite variable over time, and is probably a function of many factors, including fuel prices (unassociated sets involve more searching time and thus tend to bring higher fuel costs than FAD sets) and market conditions (*e.g.*, FAD fishing, which tends to result in greater catches of lower-value skipjack tuna and smaller yellowfin tuna and bigeye tuna than unassociated sets, might be more attractive and profitable when canneries are not rejecting small fish). Thus, the costs of complying with the FAD restrictions would depend on a variety of factors.

In 2010–2013, the last 4 years for which complete data are available and for which there was 100 percent observer coverage, the U.S. WCPO purse seine fleet made about 39 percent of its sets on FADs. During the months when setting on FADs was allowed, the percentage was about 58 percent. The fact that the fleet has made such a substantial portion of its sets on FADs indicates that prohibiting the use of FADs in the specified areas and periods could bring substantial costs and/or revenue losses.

To mitigate these impacts, vessel operators might choose to schedule their routine vessel and equipment maintenance during the FAD prohibition periods. However, the limited number of vessel maintenance facilities in the region might constrain vessel operators' ability to do this. It also is conceivable that some vessels might choose not to fish at all during the FAD prohibition periods rather than fish without the use of FADs. Observations of the fleet's behavior in 2009–2013, when FAD prohibition periods were in effect, do not suggest that either of these responses occurred to an appreciable degree. The proportion of the fleet that fished during the two- and three-month FAD prohibition periods of 2009–2013 did not appreciably differ from the proportion that fished during the same months in the years 1997–2008, when no FAD prohibition periods were in place.

The proposed FAD restrictions for 2016 would be similar to those in place in 2013–2015, except that there would be a limit of 2,522 FAD sets instead of the October FAD prohibition period that was in place in 2013–2015. 2016 is an unusual year in that SPTT licenses for 2016 were not issued until March, and the number of licensed vessels (34 as of March 2016) is fewer than in recent years. Thus, there has been relatively little purse seine fishing effort to date in the Convention Area in 2016. As a result, the expected amount of fishing effort in the Convention Area in 2016 is expected to be substantially less than in recent years. Consequently, the 2,522 FAD set limit would be less constraining than it would be if fishing effort were greater. For example, if total fishing effort in 2016 is 5,000 fishing days (about 62% of the average in 2010–2013), and the average number of sets made per fishing day is the same as in 2010–2013 (0.97), and the average number of all sets that are FAD sets ("FAD set ratio") during periods when FAD sets are allowed is the same as in 2010–2013 (58%), and if fishing effort is evenly distributed through the year, then the number of FAD sets expected in 2016 under the proposed rule would be about 2,130, somewhat less than the limit of 2,522. Under the assumptions described above, the limit of 2,522 FAD sets would start to become constraining at a total fishing effort level of 5,900 fishing days.

The effects of the proposed FAD restrictions in 2017 would likely be greater than in 2016 because of the additional prohibition on setting on FADs on the high seas. The magnitude of that additional impact cannot be predicted, but as an indication of the additional impact, in 2010–2013, about 10 percent of the fleet's fishing effort occurred on the high seas. As in 2016, the impact of the 2,522 FAD set limit in 2017 would be primarily a function of the fleet's total level of fishing effort. Given the uncertainty related to the future of the SPTT, fishing effort in 2017 is very difficult to predict. As described above for 2016, the limit would start to become constraining at a fishing effort level of about 5,900 fishing days, but in 2017 that threshold would be applicable only in the portion of the Convention Area that is not high seas (again, about 10 percent of fishing effort has occurred on the high seas in recent years).

In summary, the economic impacts of the FAD prohibition periods and FAD set limits in 2016 and 2017 and the prohibition on using FADs on the high seas throughout 2017 cannot be quantified, but they could be substantial. Their magnitude would depend in part on market conditions, oceanic conditions, and the fleet's fishing effort in 2016 and 2017, which will be determined in part by any limits on allowable levels of fishing effort in foreign EEZs and on the high seas in the Convention Area.

3. Longline Bigeye Tuna Catch Limits for 2016–2017

This element of the proposed rule would not establish any new reporting or recordkeeping requirements. The new compliance requirement would be for affected vessel owners and operators to cease retaining, landing, and transshipping bigeye tuna caught with longline gear in the Convention Area if and when the bigeye tuna catch limit is reached in 2016 (3,554 mt) or 2017 (3,345 mt), for the remainder of the calendar year, subject to the exceptions and provisos described in other sections of this **SUPPLEMENTARY INFORMATION** section of the preamble. Although the restrictions that would come into effect in the event the catch limit is reached would not prohibit longline fishing, *per se*, they are sometimes referred to in this analysis as constituting a fishery closure.

Fulfillment of this requirement is not expected to require any professional skills that the vessel owners and operators do not already possess. The costs of complying with this requirement are described below to the extent possible.

Complying with this element of the proposed rule could cause foregone fishing opportunities and result in associated economic losses in the event that the bigeye tuna catch limit is reached in 2016 or 2017 and the restrictions on retaining, landing, and transshipping bigeye tuna are imposed for portions of either or both of those years. These costs cannot be projected quantitatively with any certainty. The proposed limits of 3,554 mt for 2016 and 3,345 mt for 2017 can be compared to catches in 2005–2008, before limits were in place. The average annual catch in that period was 4,709 mt. Based on that history, as well as fishing patterns in 2009–2015, when limits were in place, there appears to be a relatively high likelihood of the proposed limits being reached in 2016 and 2017. 2015 saw exceptionally high catches of bigeye tuna. Although final estimates for 2015 are not available, the limit of 3,502 mt was estimated to have been reached by, and the fishery was closed on, August 5 (see temporary rule published July 28, 2015; 80 FR 44883). The fishery was subsequently re-opened for vessels included in agreements with the governments of the CNMI and Guam under regulations implementing Amendment 7 to the Fishery Ecosystem

Plan for Pelagic Fisheries of the Western Pacific Region (Pelagics FEP) (50 CFR 665.819). If bigeye tuna catch patterns in 2016 or 2017 are like those in 2005–2008, the limits would likely be reached in the fourth quarter of the year. If catches are more accelerated, as in 2015, the limit could be reached in the third quarter of the year.

If the bigeye tuna limit is reached before the end of 2016 or 2017 and the Convention Area longline bigeye tuna fishery is consequently closed for the remainder of the calendar year, it can be expected that affected vessels would shift to the next most profitable fishing opportunity (which might be not fishing at all). Revenues from that next best alternative activity reflect the opportunity costs associated with longline fishing for bigeye tuna in the Convention Area. The economic cost of the proposed rule would not be the direct losses in revenues that would result from not being able to fish for bigeye tuna in the Convention Area, but rather the difference in benefits derived from that activity and those derived from the next best activity. The economic cost of the proposed rule on affected entities is examined here by first estimating the direct losses in revenues that would result from not being able to fish for bigeye tuna in the Convention Area as a result of the catch limit being reached. Those losses represent the upper bound of the economic cost of the proposed rule on affected entities. Potential next-best alternative activities that affected entities could undertake are then identified in order to provide a (mostly qualitative) description of the degree to which actual costs would be lower than that upper bound.

Upper bounds on potential economic costs can be estimated by examining the projected value of longline landings from the Convention Area that would not be made as a result of reaching the limit. For this purpose, it is assumed that, absent this proposed rule, bigeye tuna catches in the Convention Area in each of 2016 and 2017 would be 5,000 mt, slightly more than the average in 2005–2008. Under this scenario, imposition of limits of 3,554 mt for 2016 and 3,345 mt for 2017 would result in 29 percent and 33 percent less bigeye tuna being caught in those two years, respectively, than under no action. In the deep-set fishery, catches of marketable species other than bigeye tuna would likely be affected in a similar way if vessels do not shift to alternative activities. Assuming for the moment that ex-vessel prices would not be affected by a fishery closure, under the proposed rule, revenues in 2016 and 2017 to entities that participate exclusively in the deep-set fishery would be approximately 29 and 33 percent less than under no action in 2016 and 2017, respectively. Average annual ex-vessel revenues (from all species) per mt of bigeye tuna caught during 2005–2008 were about $14,190/mt (in 2014 dollars, derived from the latest available annual report on the pelagic fisheries of the western Pacific Region (Western Pacific Regional Fishery Management Council, 2014, Pelagic Fisheries of the Western Pacific Region: 2012 Annual Report. Honolulu, Western Pacific Fishery Management Council). If there are 128 active vessels in the fleet, as there were during 2005–2008, on average, then under the no-action scenario of fleet-wide annual catches of 5,000 mt, each vessel would catch 39 mt/yr, on average. Reductions of 29 percent and 33 percent in 2016 and 2017, respectively, as a result of the proposed limits would be about 11 mt and 13 mt, respectively. Applying the average ex-vessel revenues (from all species) of $14,190 per mt of bigeye tuna caught, the reductions in ex-vessel revenue per vessel would be $160,000 and $183,000, on average, for 2016 and 2017, respectively.

In the shallow-set fishery, affected entities would bear limited costs in the event of the limit being reached (but most affected entities also participate in the deep-set fishery and might bear costs in that fishery, as described below). The cost would be about equal to the revenues lost from not being able to retain or land bigeye tuna captured while shallow-setting in the Convention Area, or the cost of shifting to shallow-setting in the eastern Pacific Ocean (EPO), which is to the east of 150 degrees W. longitude, whichever is less. In the fourth calendar quarters of 2005–2008, almost all shallow-setting effort took place in the EPO, and 97 percent of bigeye tuna catches were made there, so the cost of a bigeye tuna fishery closure to shallow-setting vessels would appear to be very limited. During 2005–2008, the shallow-set fishery caught an average of 54 mt of bigeye tuna per year from the Convention Area. If the proposed bigeye tuna catch limit is reached even as early as July 31 in 2016 or 2017, the Convention Area shallow-set fishery would have caught at that point, based on 2005–2008 data, on average, 99 percent of its average annual bigeye tuna catches. Imposition of the landings restriction at that point in 2016 or 2017 would result in the loss of revenues from approximately 0.5 mt (1 percent of 54 mt) of bigeye tuna, which, based on recent ex-vessel prices, would be worth no more than $5,000. Thus, expecting about 27 vessels to engage in the shallow-set fishery (the annual average in 2005–2012), the average of those potentially lost annual revenues would be no more than $200 per vessel. The remainder of this analysis focuses on the potential costs of compliance in the deep-set fishery.

It should be noted that the impacts on affected entities' profits would be less than impacts on revenues when considering the costs of operating vessels, because costs would be lower if a vessel ceases fishing after the catch limit is reached. Variable costs can be expected to be affected roughly in proportion to revenues, as both variable costs and revenues would stop accruing once a vessel stops fishing. But affected entities' costs also include fixed costs, which are borne regardless of whether a vessel is used to fish—*e.g.*, if it is tied up at the dock during a fishery closure. Thus, profits would likely be adversely impacted proportionately more than revenues.

As stated previously, actual compliance costs for a given entity might be less than the upper bounds described above, because ceasing fishing would not necessarily be the most profitable alternative opportunity when the catch limit is reached. Two alternative opportunities that are expected to be attractive to affected entities include: (1) Deep-set longline fishing for bigeye tuna in the Convention Area in a manner such that the vessel is considered part of the longline fishery of American Samoa, Guam, or the CNMI; and (2) deep-set longline fishing for bigeye tuna and other species in the EPO. These two opportunities are discussed in detail below. Four additional opportunities are: (3) Shallow-set longline fishing for swordfish (for deep-setting vessels that would not otherwise do so), (4) deep-set longline fishing in the Convention Area for species other than bigeye tuna, (5) working in cooperation with vessels operating as part of the longline fisheries of the Participating Territories—specifically, receiving transshipments at sea from them and delivering the fish to the Hawaii market, and 6) vessel repair and maintenance. A study by NMFS of the effects of the WCPO bigeye tuna longline fishery closure in 2010 (Richmond, L., D. Kotowicz, J. Hospital and S. Allen, 2015, Monitoring socioeconomic impacts of Hawai'i's 2010 bigeye tuna closure: Complexities of local management in a global fishery, Ocean & Coastal Management 106:87–96) did not identify the occurrence of any alternative activities that vessels engaged in during the closure, other than deep-setting for bigeye tuna in the EPO, vessel maintenance and repairs, and granting lengthy vacations to employees. Based on those findings, NMFS expects that alternative opportunities (3), (4), (5) and (6) are probably unattractive relative to the first two alternatives, and are not discussed here in any further detail. NMFS recognizes that vessel maintenance and repairs and granting lengthy vacations to employees are two alternative activities that might be taken advantage of if the fishery is closed, but no further analysis of their mitigating effects is provided here.

Before examining in detail the two potential alternative fishing opportunities that would appear to be the most attractive to affected entities, it is important to note that under the proposed rule, once the limit is reached and the WCPO bigeye tuna fishery is closed, fishing with longline gear both inside and outside the Convention Area during the same trip would be prohibited (except in the case of a fishing trip that is in progress when the limit is reached and the restrictions go into effect). For example, after the restrictions go into effect, during a given fishing trip, a vessel could be used for longline fishing for bigeye tuna in the EPO or for longline fishing for species other than bigeye tuna in the Convention Area, but not for both. This reduced operational flexibility would bring costs, since it would constrain the potential profits from alternative opportunities. Those costs cannot be quantified.

A vessel could take advantage of the first alternative opportunity (deep-setting for bigeye tuna in a manner such that the vessel is considered part of the longline fishery of one of the three U.S. Participating Territories), by three possible methods: (a) Landing the bigeye tuna in one of the three Participating Territories, (b) holding an American Samoa Longline Limited Access Permit, or (c) being considered part of a Participating Territory's longline fishery, by agreement with one or more of the three Participating Territories under the regulations implementing Amendment 7 to the Pelagics FEP (50 CFR 665.819). In the first two circumstances, the vessel would be considered part of the longline fishery of the Participating Territory only if the bigeye tuna were not caught in the portion of the U.S. EEZ around the Hawaiian Islands and were landed by a U.S. vessel operating in compliance with a permit issued under the regulations implementing the Pelagics FEP or the Fishery Management Plan for U.S. West Coast Fisheries for Highly Migratory Species.

With respect to the first method of engaging in alternative opportunity 1 (1.a.) (landing the bigeye tuna in one of the Participating Territories), there are three potentially important constraints. First, whether the fish are landed by the vessel that caught the fish or by a vessel to which the fish were transshipped, the costs of a vessel transiting from the traditional fishing grounds in the vicinity of the Hawaiian Archipelago to one of the Participating Territories would be substantial. Second, none of these three locales has large local consumer markets to absorb substantial additional landings of fresh sashimi-grade bigeye tuna. Third, transporting the bigeye tuna from these locales to larger markets, such as markets in Hawaii, the U.S. west coast, or Japan, would bring substantial additional costs and risks. These cost constraints suggest that this alternative opportunity has limited potential to mitigate the economic impacts of the proposed rule on affected small entities.

The second method of engaging in the first alternative opportunity (1.b.) (having an American Samoa Longline Limited Access Permit), would be available only to the subset of the Hawaii longline fleet that has both Hawaii and American Samoa longline permits (dual permit vessels). Vessels that do not have both permits could obtain them if they meet the eligibility requirements and pay the required costs. For example, the number of dual permit vessels increased from 12 in 2009, when the first WCPO bigeye tuna catch limit was established, to 20 in both 2011 and 2012. The previously cited NMFS study of the 2010 fishery closure (Richmond et al. 2015) found that bigeye tuna landings of dual permit vessels increased substantially after the start of the closure on November 22, 2010, indicating that this was an attractive opportunity for dual permit vessels, and suggesting that those entities might have benefitted from the catch limit and the closure.

The third method of engaging in the first alternative opportunity (1.c.) (entering into an Amendment 7 agreement), was also available in 2011–2015 (in 2011–2013, under section 113(a) of Public Law 112–55, 125 Stat. 552 *et seq.*, the Consolidated and Further Continuing Appropriations Act, 2012, continued by Public Law 113–6, 125 Stat. 603, section 110, the Department of Commerce Appropriations Act, 2013; hereafter, "section 113(a)"). As a result of agreements that were in place in 2011–2014, the WCPO bigeye tuna fishery was not closed in any of those four years because the annual limit for U.S. longline fisheries adopted by the WCPFC was not reached. In 2015 the fishery was closed in August but then reopened when agreements with the CNMI, and later with Guam, went into effect. Participation in an Amendment 7 agreement would likely not come without costs to fishing businesses. As an indication of the possible cost, the terms of the agreement between American Samoa and the members of the Hawaii Longline Association (HLA) in effect in 2011 and 2012 included payments totaling $250,000 from the HLA to the Western Pacific Sustainable Fisheries Fund, equal to $2,000 per vessel. It is not known how the total cost was allocated among the members of the HLA, so it is possible that the owners of particular vessels paid substantially more than or less than $2,000.

The second alternative opportunity (2) (deep-set fishing for bigeye tuna in the EPO), would be an option for affected entities only if it is allowed under regulations implementing the decisions of the Inter-American Tropical Tuna Commission (IATTC). Annual longline bigeye tuna catch limits have been in place for the EPO in most years since 2004. Since 2009, a bigeye tuna catch limit of 500 mt for 2016 has applied to U.S. longline vessels greater than 24 meters (m) in length (50 CFR 300.25), and the limits were reached in 2013 (November 11), 2014 (October 31), and 2015 (August 12). The highly seasonal nature of bigeye tuna catches in the EPO and the relatively high inter-annual variation in catches prevents NMFS from making a useful prediction of whether and when the limit in 2016 is likely to be reached. However, the trend in 2013–2015 suggests a relatively high likelihood of it being reached in 2016. If it is reached, this alternative opportunity would not be available for large longline vessels, which constitute about a quarter of the fleet. Currently there is no limit in place for 2017; the IATTC would have to take further action to adopt a limit for 2017, which NMFS would then need to implement.

Historical fishing patterns can provide an indication of the likelihood of affected entities making use of the opportunity of deep-setting in the EPO in the event of a closure in the WCPO. The proportion of the U.S. fishery's annual bigeye tuna catches that were captured in the EPO from 2005 through 2008 ranged from 2 percent to 22 percent, and averaged 11 percent. In 2005–2007, that proportion ranged from 2 percent to 11 percent, and may have been constrained by the IATTC-adoped bigeye tuna catch limits established by NMFS (no limit was in place for 2008). Prior to 2009, most of the U.S. annual bigeye tuna catch by longline vessels in the EPO typically was made in the second and third quarters of the year; in 2005–2008 the percentages caught in the first, second, third, and fourth quarters were 14, 33, 50, and 3 percent, respectively. These data demonstrate two historical patterns—that relatively little of the bigeye tuna catch in the longline fishery was typically taken in the EPO (11 percent in 2005–2008, on average), and that most EPO bigeye tuna catches were made in the second and third quarters, with relatively few catches in the fourth quarter when the proposed catch limit would most likely be reached. These two patterns suggest that there could be substantial costs for at least some affected entities that shift to deep-set fishing in the EPO in the event of a closure in the WCPO. On the other hand, fishing patterns since 2008 suggest that a substantial shift in deep-set fishing effort to the EPO could occur. In 2009, 2010, 2011, 2012, 2013, and 2014, the proportions of the fishery's annual bigeye tuna catches that were captured in the EPO were about 16, 27, 23, 19, 36, and 36 percent, respectively, and most bigeye tuna catches in the EPO were made in the latter half of the calendar years.

The NMFS study of the 2010 closure (Richmond et al. 2015) found that some businesses—particularly those with smaller vessels—were less inclined than others to fish in the EPO during the closure because of the relatively long distances that would need to be travelled in the relatively rough winter ocean conditions. The study identified a number of factors that likely made fishing in the EPO less lucrative than fishing in the WCPO during that part of the year, including fuel costs and the need to limit trip length in order to maintain fish quality and because of limited fuel storage capacity.

In addition to affecting the volume of landings of bigeye tuna and other species, the proposed catch limits could affect fish prices, particularly during a fishery closure. Both increases and decreases appear possible. After a limit is reached and landings from the WCPO are prohibited, ex-vessel prices of bigeye tuna (*e.g.,* that are caught in the EPO or by vessels in the longline fisheries of the three U.S. Participating Territories), as well as of other species landed by the fleet, could increase as a result of the constricted supply. This would mitigate economic losses for vessels that are able to continue fishing and landing bigeye tuna during the closure. For example, the NMFS study of the 2010 closure (Richmond et al. 2015) found that ex-vessel prices during the closure in December were 50 percent greater than the average during the previous five Decembers. (It is emphasized that because it was an observational study, neither this nor other observations of what occurred during the closure can be affirmatively linked as effects of the fishery closure.)

Conversely, a WCPO bigeye tuna fishery closure could cause a decrease in ex-vessel prices of bigeye tuna and other products landed by affected entities if the interruption in the local supply prompts the Hawaii market to shift to alternative (*e.g.,* imported) sources of bigeye tuna. Such a shift could be temporary—that is, limited to 2016 and/or 2017—or it could lead to a more permanent change in the market (*e.g.,* as a result of wholesale and retail buyers wanting to mitigate the uncertainty in the continuity of supply from the Hawaii longline fisheries). In the latter case, if locally caught bigeye tuna fetches lower prices because of stiffer competition with imported bigeye tuna, then ex-vessel prices of local product could be depressed indefinitely. The NMFS study of the 2010 closure (Richmond et al. 2015) found that a common concern in the Hawaii fishing community prior to the closure in November 2010 was retailers having to rely more heavily on imported tuna, causing imports to gain a greater market share in local markets. The study found this not to have been borne out, at least not in 2010, when the evidence gathered in the study suggested that few buyers adapted to the closure by increasing their reliance on imports, and no reports or indications were found of a dramatic increase in the use of imported bigeye tuna during the closure. The study concluded, however, that the 2010 closure caused buyers to give increased consideration to imports as part of their business model, and it was predicted that tuna imports could increase during any future closure. To the extent that ex-vessel prices would be reduced by this action, revenues earned by affected entities would be affected accordingly, and these impacts could occur both before and after the limit is reached, and as described above, possibly after 2017.

The potential economic effects identified above would vary among individual business entities, but it is not possible to predict the range of variation. Furthermore, the impacts on a particular entity would depend on both that entity's response to the proposed rule and the behavior of other vessels in the fleet, both before and after the catch limit is reached. For example, the greater the number of vessels that take advantage—before the limit is reached—of the first alternative opportunity (1), fishing as part of one of the Participating Territory's fisheries, the lower the likelihood that the limit would be reached. The fleet's behavior in 2011 and 2012 is illustrative. In both those years, most vessels in the Hawaii fleet were included in a section 113(a) arrangement with the government of American Samoa, and as a consequence, the U.S. longline catch limit was not reached in either year. Thus, none of the vessels in the fleet, including those not included in the section 113(a) arrangements, were prohibited from fishing for bigeye tuna in the Convention Area at any time during those two years. The fleet's experience in 2010 (before opportunities under section 113(a) or Amendment 7 to the Pelagics FEP were available) provides another example of how economic impacts could be distributed among different entities. In 2010 the limit was reached and the WCPO bigeye tuna fishery was closed on November 22. As described above, dual permit vessels were able to continue fishing outside the U.S. EEZ around the Hawaiian Archipelago and benefit from the relatively high ex-vessel prices that bigeye tuna fetched during the closure.

In summary, based on potential reductions in ex-vessel revenues, NMFS has estimated that the upper bound of potential economic impacts of the proposed rule on affected longline fishing entities could be roughly $160,000 per vessel, on average, in 2016 and $183,000 per vessel, on average, in 2017. The actual impacts to most entities are likely to be substantially less than those upper bounds, and for some entities the impacts could be neutral or positive (*e.g.,* if one or more Amendment 7 agreements are in place in 2016 and 2017 and the terms of the agreements are such that the U.S. longline fleet is effectively unconstrained by the catch limits).

Disproportionate Impacts

As indicated above, all affected entities are believed to be small entities, so small entities would not be disproportionately affected relative to large entities. Nor would there be disproportionate economic impacts based on home port.

Purse seine vessels would be impacted differently than longline vessels, but whether the impacts would be disproportional between the two gear types cannot be determined.

For the longline sector, as described above, there could be disproportionate impacts according to vessel type and size and the type of fishing permits held. A vessel with both a Hawaii Longline Limited Access Permit and an American Samoa Longline Limited Access Permit would be considered part of the American Samoa longline fishery (except when fishing in the U.S. EEZ around the Hawaiian Archipelago), so it would not be subject to the proposed catch limits. Because the EPO bigeye tuna catch limit for 2016 applies only to vessels greater than 24 m in length, in the event that the WCPO bigeye tuna fishery is closed and the 500 mt limit is reached in the EPO, only vessels 24 m or less in length would be able to take advantage of the alternative opportunity of deep-setting for bigeye tuna in the EPO. On the other hand, smaller vessels can be expected to find it more difficult, risky, and/or costly to fish in the EPO during the relatively rough winter months than larger vessels. If there are any large entities among the affected entities, and if the vessels of the large entities are larger than those of small entities, then it is possible that small entities could be disproportionately affected relative to large entities.

Duplicating, Overlapping, and Conflicting Federal Regulations

NMFS has not identified any Federal regulations that duplicate, overlap with, or conflict with the proposed regulations.

Alternatives to the Proposed Rule

NMFS has sought to identify alternatives that would minimize the proposed rule's economic impact on small entities ("significant alternatives"). Taking no action could result in lesser adverse economic impacts than the proposed action for affected entities in the purse seine and longline fisheries (but as described below, for some affected longline entities, the proposed rule could be more economically beneficial than no-action), but NMFS does not prefer the no-action alternative, because it would be inconsistent with the United States' obligations under the Convention. Alternatives identified for each of the three elements of the proposed rule are discussed below.

1. Purse Seine Observer Requirements

NMFS has not identified any significant alternatives to the proposed purse seine observer requirements that would comport with U.S. obligations to implement the Commission decisions regarding observer coverage.

2. Purse Seine FAD Restrictions for 2016–2017

NMFS considered in detail one set of alternatives to the proposed restrictions on the use of FADs. Under CMM 2015–01, the United States could use either of two options in either of 2016 and 2017 (in addition to the three-month FAD closure periods in both years and the prohibition on FAD sets on the high seas in 2017). One option is a fourth-month FAD prohibition period, in October. The second option, proposed in this rule, is an annual limit of 2,522 FAD sets. The relative effects of the two options would depend on the total amount of fishing effort exerted by the U.S. purse seine fleet in the Convention Area in a given year. If total fishing effort is relatively high, an October FAD prohibition period would likely allow for more FAD sets than a limit of 2,522 FAD sets, and thus likely cause lesser adverse impacts. The opposite would be the case for relatively low levels of total fishing effort. For example, given the fleet's recent historical average FAD set ratio of 58 percent when FAD-setting is allowed (2010–2013), and assuming an even distribution of sets throughout the year, the estimated "breakeven" point between the two options is 6,502 total sets for the year. The levels of fishing effort in 2016 and 2017 are very difficult to predict; they will be determined largely by the level of participation in the fishery (number of vessels) and any limits imposed on fishing effort. Fishing effort in foreign zones and on the high seas in the SPTT Area is likely to be limited by the terms of arrangements under the SPTT. Fishing effort elsewhere in the Convention Area (*e.g.*, in the U.S. EEZ and on the high seas outside the Treaty Area) would be constrained by any limits established by NMFS to implement the provisions of CMM 2015–01. NMFS has not yet established or proposed any such limits for 2016 or 2017, and cannot speculate what limits it might propose, but a point of reference are the limits that were in place in 2009–2015. Those limits applied to the Effort Limit Area for Purse Seine, or ELAPS, which consists of all areas of high seas and U.S. exlusive economic zone in the Convention Area between the latitudes of 20° N. and 20° S. The limits in 2009–2013 were 2,588 fishing days per year. The limits in 2014–2015 were 1,828 fishing days per year. With respect to numbers of vessels and allowable fishing effort limits under the SPTT, 2016 is an unusual year in that SPTT licenses for 2016 were not issued until March, and the number of licensed vessels (34 as of March 2016) is fewer than in recent years. Thus, there has been relatively little purse seine fishing effort to date in the Convention Area in 2016, and NMFS expects that total fishing effort in 2016 is likely to be less than 6,502 sets (the estimated breakeven point between the two options). For reference, the average number of sets made annually in 2010–2013, when an average of 38 vessels were active in the fishery, was 7,835. The average number of fishing days made annually in 2010–2013 was 8,030, so the average number of sets made per fishing day was 0.97. Predicting the situation for 2017 is even more difficult than for 2016, but current circumstances suggest that participation in 2017 could be less than in recent years. Also, because setting on FADs on the high seas would be prohibited in 2017 under this proposed rule, the estimated breakeven point of 6,502 total sets applies not everywhere in the Convention Area, but only those portions that are not high seas. Assuming that about 10 percent of fishing effort takes place on the high seas, as in 2010–2013, the breakeven point for the Convention Area as a whole is about 7,224 total sets. Assuming 0.97 sets per fishing day, on average, as occurred in 2010–2013, this equates roughly to 7,371 fishing days. This is slightly less than the average annual fishing effort in 2010–2013 (7,835 sets; 8,030 fishing days), but again, given current circumstances and uncertainty surrounding the future of the SPTT, NMFS expects that total fishing effort in 2017 is likely to be less than that breakeven level. Based on the above expectations and assumptions for conditions in 2016 and 2017, an annual limit of 2,522 FAD sets is likely to have lesser adverse impacts on fishing businesses than a FAD prohibition period in October, in both 2016 and 2017, and NMFS prefers the proposed action for that reason.

3. Longline Bigeye Tuna Catch Limits

NMFS has not identified any significant alternatives to this element of the proposed rule, other than the no-action alternative.

List of Subjects in 50 CFR Part 300

Administrative practice and procedure, Fish, Fisheries, Fishing, Marine resources, Reporting and recordkeeping requirements, Treaties.

Dated: April 22, 2016.

Eileen Sobeck,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 300 is proposed to be amended as follows:

PART 300—INTERNATIONAL FISHERIES REGULATIONS

■ 1. The authority citation for 50 CFR part 300, continues to read as follows:

Authority: 16 U.S.C. 951 *et seq.*, 16 U.S.C. 1801 *et seq.*, 16 U.S.C. 5501 *et seq.*, 16 U.S.C. 2431 *et seq.*, 31 U.S.C. 9701 *et seq.*

■ 2. In § 300.222, add paragraph (ww) to read as follows:

§ 300.222 Prohibitions.

* * * * *

(ww) Fail to carry an observer as required in § 300.223(e).

* * * * *

■ 3. In § 300.223:

■ a. Revise paragraph (b)(1) introductory text and paragraphs (b)(2)(i) and (ii); and

■ b. Add paragraphs (b)(2)(iii) and (iv), and paragraph (e) to read as follows:

§ 300.223 Purse seine fishing restrictions.

* * * * *

(b) * * *

(1) During the periods and in the areas specified in paragraph (b)(2) of this section, owners, operators, and crew of fishing vessels of the United States shall not do any of the activities described below in the Convention Area in the area between 20° N. latitude and 20° S. latitude:

* * * * *

(2) * * *

(i) From July 1 through September 30, 2016;

(ii) From July 1 through September 30, 2017;

(iii) During any period specified in a **Federal Register** notice issued by NMFS announcing that NMFS has determined that U.S. purse seine vessels have collectively made, or are projected to make, 2,522 sets on FADs in the Convention Area in the area between 20° N. latitude and 20° S. latitude in 2016 or 2017. The **Federal Register** notice will be published at least seven days in advance of the start of the period announced in the notice. NMFS will estimate and project the number of FAD sets using vessel logbooks, and/or other information sources that it deems most appropriate and reliable for the purposes of this section; and

(iv) In any area of high seas, from January 1 through December 31, 2017.

* * * * *

(e) *Observer coverage.*

(1) A fishing vessel of the United States may not be used to fish with purse seine gear in the Convention Area without a WCPFC observer on board. This requirement does not apply to fishing trips that meet either of the following conditions:

(i) The portion of the fishing trip within the Convention Area takes place entirely within areas under the jurisdiction of a single nation other than the United States; or,

(ii) No fishing takes place during the fishing trip in the Convention Area in the area between 20° N. latitude and 20° S. latitude.

(2) Owners, operators, and crew of fishing vessels subject to paragraph (e)(1) of this section must accommodate WCPFC observers in accordance with the provisions of § 300.215(c).

(3) Meeting either of the conditions in paragraphs (e)(1)(i) and (e)(1)(ii) of this section does not exempt a fishing vessel from having to carry and accommodate a WCPFC observer pursuant to § 300.215 or other applicable regulations.

* * * * *

■ 4. In § 300.224, revise paragraph (a) to read as follows:

§ 300.224 Longline fishing restrictions.

(a) *Establishment of bigeye tuna catch limits.*

(1) During calendar year 2016 there is a limit of 3,554 metric tons of bigeye tuna that may be captured in the Convention Area by longline gear and retained on board by fishing vessels of the United States.

(2) During calendar year 2017 there is a limit of 3,345 metric tons of bigeye tuna that may be captured in the Convention Area by longline gear and retained on board by fishing vessels of the United States.

* * * * *

[FR Doc. 2016–09856 Filed 4–26–16; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 81, No. 81
Wednesday, April 27, 2016

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forest Service

Newspapers for Publication of Legal Notices in the Eastern Region

AGENCY: Forest Service, USDA.

ACTION: Notice.

SUMMARY: Forest Service administrative review procedures at 36 CFR parts 218 and 219 require agency officials to publish legal notices in newspapers of record for certain opportunities to comment and opportunities to file pre-decisional objections. Forest Service officials in the Eastern Region will publish those legal notices in the newspapers listed in the **SUPPLEMENTARY INFORMATION** section of this notice. The Eastern Region consists of Illinois, Indiana, Ohio, Michigan, Minnesota, Missouri, New Hampshire, Maine, Pennsylvania, Vermont, New York, West Virginia, and Wisconsin. As provided in 36 CFR 218 and 36 CFR 219, the public shall be advised through **Federal Register** notice, of the newspaper of record to be utilized for publishing legal notice of comment and objection opportunities required by those Parts and their associated procedures. This notice fulfills that requirement for the Eastern Region.

DATES: Use of these newspapers for purposes of publishing legal notice of opportunities to comment on proposals subject under 36 CFR part 218 and 36 CFR part 219, and notices of the opportunity to object under 36 CFR part 218 and 36 CFR part 219 shall begin the first day after the date of this publication.

FOR FURTHER INFORMATION CONTACT: Michael Tighe; Writer/Editor; 626 E. Wisconsin Avenue, Milwaukee, WI 53202. Phone: (414) 297–3439.

SUPPLEMENTARY INFORMATION: Responsible Officials in the Eastern Region will publish legal notice regarding proposed land management plans as required under 36 CFR 219.16 and legal notice regarding an opportunity to comment on proposed projects as required under 36 CFR 218.24 in the newspapers that are listed in this section by Forest Service administrative unit. Additionally, Responsible Officials in the Eastern Region will publish legal notice of the opportunity to object to a proposed project under 36 CFR part 218 or to object to a land management plan developed, amended, or revised under 36 CFR part 219 in the legal notice section of the following newspapers. Additional notice regarding an opportunity to comment or object under the above mentioned regulations may be provided in other newspapers not listed below at the sole discretion of the Responsible Official. Legal notice published in a newspaper of record of an opportunity to object is in addition to direct notice to those who have requested it and to those who have participated in planning for the project or land management plan proposal.

The timeframe for comment on a proposed action shall be based on the date of publication of the legal notice of the proposed action in the newspaper of record. The timeframe for objection shall be based on the date of publication of the legal notice of the opportunity to object in the newspaper of record.

The following newspapers will be used to provide legal notice.

Eastern Region

Regional Forester Decisions

Affecting National Forest System lands in the Eastern Region, in the states of Illinois, Indiana, Ohio, Michigan, Minnesota, Missouri, New Hampshire, Maine, Pennsylvania, Vermont, New York, West Virginia, and Wisconsin, *The Milwaukee Journal/Sentinel*, published daily in Milwaukee, Milwaukee County, Wisconsin.

Allegheny National Forest, Pennsylvania

Forest Supervisor Decisions

Warren Times Observer, Warren, Warren County, Pennsylvania

District Ranger Decisions

Bradford District: *Bradford Era*, Bradford, McKean County, Pennsylvania

Marienville District: *The Kane Republican*, Kane, McKean County, Pennsylvania

Chequamegon/Nicolet National Forest, Wisconsin

Forest Supervisor Decisions

The Northwoods River News, published Tuesdays, Thursdays, and Saturdays, Rhinelander, Oneida County, Wisconsin

District Ranger Decisions

Eagle River/Florence District: *The Northwoods River News*, published Tuesdays, Thursdays, and Saturdays, Rhinelander, Oneida County, Wisconsin

Great Divide District: *The Ashland Daily Press*, published daily in Ashland, Ashland County, Wisconsin

Medford/Park Falls District: *The Star News*, published weekly in Medford, Taylor County, Wisconsin

Washburn District: *The Ashland Daily Press*, published daily in Ashland, Ashland County, Wisconsin

Lakewood/Laona District: *The Northwoods River News*, published Tuesdays, Thursdays, and Saturdays in Rhinelander, Oneida County, Wisconsin

Chippewa National Forest, Minnesota

Forest Supervisor Decisions

Bemidji Pioneer, published daily in Bemidji, Beltrami County, Minnesota

District Ranger Decisions

Blackduck District: *The American*, published weekly in Blackduck, Beltrami County, Minnesota

Deer River District: *The Western Itasca Review*, published weekly in Deer River, Itasca County, Minnesota

Walker District: *The Pilot/Independent*, published weekly in Walker, Cass County, Minnesota

Green Mountain National Forest, Vermont

Forest Supervisor Decisions

The Rutland Herald, published daily in Rutland, Rutland County, Vermont

District Ranger Decisions

Manchester, Middlebury and Rochester Districts: *The Rutland Herald*, published daily in Rutland, Rutland County, Vermont

Finger Lakes National Forest, New York

Forest Supervisor Decisions

The Ithaca Journal, published daily in Ithaca, Tompkins County, New York

District Ranger Decisions

Hector District: *The Ithaca Journal,* published daily in Ithaca, Tompkins County, New York

Hiawatha National Forest, Michigan

Forest Supervisor Decisions

The Daily Press, published daily in Escanaba, Delta County, Michigan

District Ranger Decisions

Rapid River District: *The Daily Press,* published daily in Escanaba, Delta County, Michigan
Manistique District: *The Daily Press,* published daily in Escanaba, Delta County, Michigan
Munising District: *The Mining Journal,* published daily in Marquette, Marquette County, Michigan
St. Ignace District: *The Sault News,* published daily in Sault Ste. Marie, Chippewa County, Michigan
Sault Ste. Marie District: *The Sault News,* published daily in Sault Ste.Marie, Chippewa County, Michigan

Hoosier National Forest, Indiana

Forest Supervisor Decisions

The Hoosier Times, published in Bloomington, Monroe County, and Bedford, Lawrence County, Indiana

District Ranger Decisions

Brownstown District: *The Hoosier Times,* published in Bloomington, Monroe County, and Bedford, Lawrence County, Indiana
Tell City District: *The Perry County News,* published in Tell City, Perry County, Indiana

Huron-Manistee National Forest, Michigan

Forest Supervisor Decisions

Cadillac News, published daily in Cadillac, Wexford County, Michigan

District Ranger Decisions

Baldwin-White Cloud Districts: *Lake County Star,* published weekly in Baldwin, Lake County, Michigan
Cadillac-Manistee Districts: *Manistee News Advocate,* published daily in Manistee, Manistee County, Michigan
Mio District: *Oscoda County Herald,* published weekly in Mio, Oscoda County, Michigan
Huron Shores District: *Oscoda Press,* published weekly in Oscoda, Iosco County, Michigan

Mark Twain National Forest, Missouri

Forest Supervisor Decisions

The Rolla Daily News, published Monday through Saturday in Rolla, Phelps County, Missouri

District Ranger Decisions

Ava/Cassville/Willow Springs District: *Springfield News-Leader,* published daily in Springfield, Greene County, Missouri
Cedar Creek District: *Fulton Sun,* published daily in Fulton, Callaway County, Missouri
Eleven Point District: *Prospect News,* published weekly (Wednesday) in Doniphan, Ripley County, Missouri
Rolla District: *Houston Herald,* published weekly (Thursdays) in Houston, Texas County, Missouri
Houston District: *Houston Herald,* published weekly (Thursdays) in Houston, Texas County, Missouri
Poplar Bluff District: *Daily American Republic,* published daily in Poplar Bluff, Butler County, Missouri
Potosi District: *The Independent-Journal,* published weekly (Thursday) in Potosi, Washington County, Missouri
Fredericktown District: *The Democrat-News,* published weekly (Wednesday) in Fredericktown, Madison County, Missouri
Salem District: *The Salem News,* published weekly (Tuesday) in Salem, Dent County, Missouri

Midewin Tallgrass Prairie, Illinois

Prairie Supervisor Decisions

The Herald News, published daily in Joliet, Will County, Illinois

Monongahela National Forest, West Virginia

Forest Supervisor Decisions

The Inter-Mountain, published daily in Elkins, Randolph County, West Virginia

District Ranger Decisions

Cheat-Potomac District: *The Grant County Press,* published weekly in Petersburg, Grant County, West Virginia
Gauley District: *The Nicholas Chronicle,* published weekly in Summersville, Nicholas County, West Virginia
Greenbrier District: *The Pocahontas Times,* published weekly in Marlinton, Pocahontas County, West Virginia
Marlinton-White Sulphur District: *The Pocahontas Times,* published weekly in Marlinton, Pocahontas County, West Virginia

Ottawa National Forest, Michigan

Forest Supervisor Decisions

The Ironwood Daily Globe, published in Ironwood, Gogebic County, Michigan; except, for those projects located solely within the Iron River District; *The Reporter,* published in Iron River, Iron County, Michigan

District Ranger Decisions

Bergland, Bessemer, Kenton, Ontonagon and Watersmeet Districts: *The Ironwood Daily Globe,* published in Ironwood, Gogebic County, Michigan
Iron River District: *The Reporter,* published in Iron River, Iron County, Michigan

Shawnee National Forest, Illinois

Forest Supervisor Decisions

Southern Illinoisan, published daily in Carbondale, Jackson County, Illinois

District Ranger Decisions

Hidden Springs and Mississippi Bluffs Districts: *Southern Illinoisan,* published daily in Carbondale, Jackson County, Illinois

Superior National Forest, Minnesota

Forest Supervisor Decisions

Duluth News-Tribune, published daily in Duluth, St Louis County, Minnesota

District Ranger Decisions

Gunflint District: *Cook County News-Herald,* published weekly in Grand Marais, Cook County, Minnesota
Kawishiwi District: *Ely Echo,* published weekly in Ely, St Louis County, Minnesota
LaCroix District: *Mesabi Daily News,* published daily in Virginia, St Louis County, Minnesota
Laurentian District: *Mesabi Daily News,* published daily in Virginia, St Louis County, Minnesota
Tofte District: *Duluth News-Tribune,* published daily in Duluth, St Louis County, Minnesota

Wayne National Forest, Ohio

Forest Supervisor Decisions

Athens Messenger, published daily in Athens, Athens County, Ohio

District Ranger Decisions

Athens District-Marietta Unit: *Athens Messenger,* published daily in Athens, Athens County, Ohio
Ironton District: *The Ironton Tribune,* published daily in Ironton, Lawrence County, Ohio

White Mountain National Forest, New Hampshire and Maine

Forest Supervisor Decisions

The New Hampshire Union Leader, published daily in Manchester, County of Hillsborough, New Hampshire

District Ranger Decisions

Androscoggin District: *The New Hampshire Union Leader,* published daily in Manchester, County of Hillsborough, New Hampshire; except, for those projects located solely within the State of Maine; the *Lewiston Sun-Journal,* published daily in Lewiston, County of Androscoggin, Maine

Pemigewasset District: *The New Hampshire Union Leader,* published daily in Manchester, County of Hillsborough, New Hampshire

Saco District: *The New Hampshire Union Leader,* published daily in Manchester, County of Hillsborough, New Hampshire; except, for those projects located solely within the State of Maine; the *Lewiston Sun-Journal,* published daily in Lewiston, County of Androscoggin, Maine

Dated: April 20, 2016.

Kathleen Atkinson,

Regional Forester.

[FR Doc. 2016–09806 Filed 4–26–16; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

San Juan Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The San Juan Resource Advisory Committee (RAC) will meet in Durango Colorado. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act. RAC information can be found at the following Web site: *http://cloudapps-usda-gov.force.com/FSSRS/RAC_Page?id=001t0000002JcvFAAS.*

DATES: The meeting will be held at 9:00 a.m. on Tuesday, May 24, 2016.

All RAC meetings are subject to cancellation. For status of meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

ADDRESSES: The meeting will be held at the San Juan Public Lands Center, Sonoran Meeting Rooms, 15 Burnett Court, Durango, Colorado.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION.** All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at San Juan Public Lands Center. Please call ahead to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Ann Bond, RAC Coordinator, by phone at 970–385–1219 or via email at *abond@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

1. Review previously approved projects, and

2. Review current project proposals to be recommended for funding under the Title II provision of the Secure Rural Schools Act.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by May 10, 2016, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time for oral comments must be sent to Ann Bond, RAC Coordinator, San Juan Public Lands Center, 15 Burnett Court, Durango, Colorado 81301; by email to *abond@fs.fed.us,* or via facsimile to 970–375–2331.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices, or other reasonable accommodation. For access to the facility or proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT.** All reasonable accommodation requests are managed on a case by case basis.

Dated: April 21, 2016.

Richard Bustamante,

Acting San Juan National Forest Supervisor.

[FR Doc. 2016–09857 Filed 4–26–16; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

RIN 0596–AC82

Ecosystem Restoration Policy

AGENCY: Forest Service, USDA.

ACTION: Notice of final directive.

SUMMARY: The Forest Service is issuing a permanent Ecosystem Restoration policy that replaces the Interim Directive, "Ecological Restoration and Resilience Policy," in Forest Service Manual (FSM) 2020. The policy provides broad guidance for restoring ecosystems on National Forest System lands so that they are self-sustaining and, if subject to disturbances or environmental change, have the ability to reorganize and renew themselves. This policy recognizes the adaptive capacity of restored ecosystems, the role of natural disturbances, and uncertainty related to climate and other environmental factors.

DATES: This directive is in effect May 27, 2016.

FOR FURTHER INFORMATION CONTACT: Jim Alegria, Forest Management Staff, USDA Forest Service, Mailstop 1103, 1400 Independence Avenue SW., Washington, DC 20250; phone: 202–205–1787.

Individuals who use telecommunications devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Background and Need for the Directive

The need for reestablishing and retaining resilience of National Forest System lands and resources to achieve sustainable management and provide a broad range of ecosystem services is widely recognized, and the Forest Service has conducted restoration-related activities for decades. In 2008, the Chief of the Forest Service determined that a national policy was needed to ensure a consistent and cohesive approach to reestablish and retain ecological resilience on National Forest System lands and for National Forest System resources. An interim directive was first issued on September 22, 2008, and was reissued on March 3, 2010, August 30, 2011, May 13, 2013, November 17, 2014, and October 15, 2015.

A notice of availability of a proposed Ecological Restoration Policy (78 FR 56202) was published in the **Federal Register** on September 12, 2013 for public review and comment. A total of 16 comments were received: Five from non-affiliated members of the public, two from State government agencies, four from the timber industry, and five from non-governmental organizations.

The Agency believes that a comprehensive policy that includes standard definitions would provide a tool for sustaining the health, diversity, and productivity of the Nation's forests and grasslands to meet the needs of present and future generations. The Forest Service is amending its directives by establishing a new title in the Forest Service Manual, FSM 2020: Ecosystem Restoration. The ecosystem restoration directive applies to all National Forest System resource management programs. The intent is to provide a clear, science-based policy to guide management actions where restoration is appropriate.

This policy provides that "ecosystem restoration" can be carried out through the processes of ecological restoration and functional restoration. Ecological restoration typically focuses on recreating the ecosystem conditions that were present prior to European influences. However, some ecosystems may have been altered to such an extent that reestablishing pre-European conditions may be ecologically or economically infeasible. In such circumstances, management goals and activities should create functioning ecosystems in the context of changing conditions through the process called functional restoration.

Ecosystem restoration can be achieved by a range of management activities, such as forest thinning to reduce tree density, prescribed fire to reduce fuel buildup, replacing culverts to better connect streams, or fencing to restrict disturbances. Ecosystem restoration may include manipulating or protecting terrestrial and aquatic ecosystems to assist in their recovery or adaptation to changing environmental conditions. Monitoring and evaluation of restoration projects are essential adaptive management steps for achieving sustainable ecosystems. Ecosystem restoration is a process that can help to achieve the multiple-use mission of the Forest Service, but not all management activities on National Forests and Grasslands require a restoration objective. For example, hazardous fuels reduction to reduce wildfire risk to communities may require a silvicultural treatment that is not restoration. Additionally, not all NFS lands need to be restored. Restoration activities will complement management to maintain conditions in areas with ecological integrity. The Agency may incorporate restoration objectives to the extent that they are ecologically and economically feasible and support achieving desired conditions or management objectives including multiple uses and ecosystem services such as carbon storage, energy development, recreation use, livestock grazing, hazardous fuels reduction, soil formation, watershed, wildlife, and timber production conducted in accordance with applicable laws, regulations, and policies.

Restoration may be helpful in managing for climate change by maintaining carbon stocks provided by the national forests. The relationship between restoration and carbon is complex. The Forest Service manages carbon through managing the health and promoting the adaptive capacity of our forests in the face of frequent, intense, and severe disturbances. Management can also be designed to recover, maintain, and enhance carbon stocks, through restoration management practices. The Forest Service also maintains and restores carbon through treatment activities that restore the age and size-class patterns across the landscape. Some of the activities that the Forest Service undertakes for restoring resiliency and function in the National Forest System, such as thinning of forest stands and prescribed burning, can result in a release of carbon in the short term. In the long term, however, these activities should make the forest more resilient to disturbances such as wildfire, insects, and drought therefore reducing the risk to carbon stocks.

The expectation is that forest restoration treatments will lead to forest resilience and a lower probability of a catastrophic disturbance and that consequently, more carbon will continue to be sequestered than would otherwise occur without the treatment. How quickly the carbon pools sequester carbon depends on several factors including the amount of carbon removed or lost in the treatment, the productivity of the ecosystem, the site conditions, the climate variables following the treatment, and the stand structure. Due to the many variables and assumptions regarding post-treatment carbon capture, research on whether restoration increases carbon stocks is inconclusive. Some studies indicate that post-treatment forest stands never catch up to the carbon stocks in untreated stands. However, other studies have concluded that treated stands lose less overall carbon in subsequent wildfire events compared to untreated stands and that reductions in wildfire severity have a significant impact on future carbon pools. Other studies have demonstrated that forest harvesting can reduce atmospheric CO_2 if the carbon accounting considers avoided emissions from fossil fuels when biomass is used for energy, or the avoided emissions and carbon storage when long-lived harvested wood products are substituted for high embodied energy materials such as steel and concrete.

The Ecosystem Restoration policy has identical definitions for key terms that are in the 2015 National Forest System, Land Management Planning Directive (FSH 1909.12, zero code, section 05). By using identical definitions, the policy ensures that within the Agency, and in dealing with the public, terms will be used and understood in the same way. The terms and definitions are: Adaptation, adaptive capacity, adaptive management, carbon pool, carbon stocks, disturbance, disturbance regime, ecological restoration (see "restoration—ecological"), functional restoration (see "restoration—functional"), ecological integrity, ecosystem, ecosystem services, landscape, natural range of variation (NRV), resilience, stressors, and sustainability.

Some of the terms defined in 2015 National Forest System, Land Management Planning Directive (FSH 1909.12, zero code, section 05) such as ecological and functional restoration, natural range of variation and resilience, merit further discussion on how they interrelate to one another. In order to construct a desired future condition for an area, one should assess past and current conditions as well as how these conditions may change into the future. Ecological restoration focuses on reestablishing the composition, structure, pattern, and ecological processes necessary to facilitate terrestrial and aquatic ecosystem sustainability, resilience, and health under current and future conditions. Assessing current and potential future conditions should result in a detailed description of the composition, structure, pattern, and ecological processes of the ecosystem as it moves along an ecological trajectory through time. Moving along a trajectory means that ecosystems are not static and may have changing characteristics.

The desired future condition of an ecosystem should be informed by an assessment of spatial and temporal variation in ecosystem characteristics under historic disturbance regimes during a specified reference period. The spatial and temporal variation of characteristics in the specified reference period is often called the natural range of variation (NRV). The NRV should be used to inform an understanding of ecosystem function and biophysical capability, the dynamic nature of ecosystems associated natural and current disturbance regimes, and potential responses to future environments resulting from climate change and increasing human uses. The NRV does not define a management target or desired condition; it provides context for understanding ecological integrity. In some situations, the desired future condition may be a restored ecosystem similar to pre-disturbance conditions where degradation and stressors are limited and minimal changes to environmental conditions are anticipated in the near future. In other situations, the desired future condition may be a restored ecosystem that departs from the NRV along a continuum from only slight to substantial but still retains some ecological components within the NRV.

Like ecological restoration, functional restoration is a process to restore degraded biotic and abiotic processes to facilitate the creation of a desired future condition. A functionally restored ecosystem, however, may look quite different than the NRV in terms of structure and composition, where the disparities cannot be easily changed because some threshold of degradation has been crossed or significant environmental drivers, such as climate or invasive species, that influenced structural and (especially) compositional development have changed. The desired outcome of a restoration treatment may incorporate concepts from both ecological and functional restoration. For example, ecological conditions for some native species, due to insects and diseases, are no longer functioning as they once functioned and cannot be restored to their previous state. There are invasive species that have become so established that they cannot be economically eradicated. Climate change may affect components of the ecosystem differently so that some components should be restored to within the NRV and others should not or cannot be restored. In these situations the objective should be to restore the abiotic and biotic processes even if the components diverge from the NRV.

Resilience is the ability of an ecosystem and its component parts to absorb, or recover from, the effects of disturbances through preservation, restoration, or improvement of its essential structures, functions, and redundancy of ecological patterns across the landscape. It is a characteristic of healthy ecosystems and a desired characteristic of a restored ecosystem.

Response to Comments on the Proposed Policy

Changes Between the Proposed and Final Policy

Based on external and internal comments, there were changes between the proposed and final policy. The major changes are listed below.

1. The title has changed from "Ecological Restoration" to "Ecosystem Restoration" in the final policy, to better align the title with the content of the final policy and the mission of the Agency.
2. The final policy adds consideration for the recovery, maintenance, and enhancement of carbon stocks associated with National Forest System lands.
3. The final policy does not change the definition of ecological restoration but does clarify the relationship of ecological restoration to functional restoration and resilience.
4. The final policy facilitates achieving long-term ecological sustainability and a broad range of ecosystem services and multiple uses to society in Objectives (FSM 2020.2).
5. The final policy uses key terms that are in the 2015 National Forest System, Land Management Planning Directive and uses the same definitions for those terms. (FSH 1909.12, zero code.
6. The final policy retains the summaries of the principal legal authorities for the policy FSM 2020.11, but now lists other statutes, without summaries, in FSM 2020.61.
7. The Executive Orders (FSM 2020.12) descriptions are eliminated and replaced with the citations to those Executive Orders in FSM 2020.63.
8. The agency removed most of FSM 2020.4 because it was redundant with the general delegations of authorities of FSM 1230. The Agency has concluded that the responsibilities for restoration belongs to those Agency employees who have the delegated authority to approve land and resource management plans, project plans, or other Forest Service activities.
9. Definitions of key terms were deleted in the final policy and replaced with a reference to the definitions in planning rule (36 CFR 219.19) and planning handbook (FSH 1909.12, Zero Code chapter, section 05).

General Comments on the Proposed Policy

Comment: Respondents questioned how the directive will help achieve national forest management objectives or how not having the directive will prevent achieving national forest management objectives. Others questioned how the directive would increase Agency effectiveness, they questioned the need for a permanent ecological restoration policy, and they questioned why there is no attempt to prioritize ecological restoration within the context of relevant laws or ecosystem components.

Response: Restoration spans a number of initiatives in various program areas, including the invasive species strategy; recovery of areas affected by high-severity fires, hurricanes, and other catastrophic disturbances; fish habitat restoration and remediation; riparian area restoration; conservation of threatened, endangered, and sensitive species; and restoration of impaired watersheds and large-scale watershed restoration projects. There was no framework to unite these various program-specific initiatives with cohesive policies and definitions. While restoration has been a long-standing Agency practice, even without a restoration policy, a cohesive policy is expected to increase the Agency's efficiency in achieving management objectives. The authority for restoring National Forest System lands derives from laws enacted by Congress that define the purpose of national forests and grasslands and direct the Forest Service to administer and manage the lands for these purposes. The major authorities are cited in FSM 2020.1. The prioritization of ecological restoration is guided by the responsible official, which is usually the forest supervisor or district ranger.

Comment: Another respondent asked how this directive will affect implementation of the 2012 planning rule.

Response: The 2012 planning rule emphasizes restoration as it guides the Forest Service in the development, amendment, and revision of land management plans. The policies, ecological principles, and definitions in this final directive are consistent with the planning rule and will also guide activities on those units that have not yet developed, amended, or revised land management plans under the planning rule, and it provides further guidance on ecosystem restoration.

Comment: Some respondents felt that the term "restoration" was too limiting and that it may not be economically or ecologically possible to achieve NRV due to factors such as climate change or severely degraded environments. The terms "ecological integrity" and "NRV" are past-focused and ignore adaptation to future climate and anthropogenic stressors.

Response: The policy has been clarified in the final directive. Emphasis has been placed on returning an impaired ecosystem to a condition of appropriate complexity and increased resilience through ecosystem restoration or functional restoration. The aim of both ecological and functional restoration is to restore degraded processes to facilitate the creation of a desired future condition. The final policy acknowledges that, when an ecosystem has been so degraded such that it is impossible or impractical to return conditions to those within the NRV, or that the projected environmental conditions will not support returning an ecosystem to be within the NRV, the *functional restoration* may be appropriate to restore ecological processes but achieve the essential functions of the ecosystem with different species composition and structure than pre-European settlement conditions. Functional restoration can sometimes serve as the best approach to restoring ecological integrity within the inherent capability of the planning area.

Comment: Other comments included that a broad-scale restoration policy fails to account for localized historic influences, that there is a lack of an active role for forest management in the policy, and that the policy would result in an underrepresentation of early seral stages on the national forests.

Response: The broad-scale or ecosystem restoration approach emphasized in the policy includes evaluating the current seral stage distribution and connectivity against the desired conditions, which may include early seral stages, specialized habitats, and historic influences. The mechanism to achieve the desired conditions are decided on a project-by-project basis and may include active forest management to restore the stand age distribution to be within NRV.

Comment: Another respondent stated that the definitions are circular: Ecological integrity is a set of conditions that are within the NRV and is relative to a historic reference period. Consequently, since the NRV defines ecological integrity, one could argue, any management action that strays from NRV is degrading the ecosystem.

Response: The management objective for any area is governed by the applicable land management plan. The land management plan must provide for social, economic, and ecological sustainability within Forest Service authority and consistent with the inherent capability of the plan area (36 CFR 219.8). NRV is "The variation of ecological characteristics and processes over scales of time and space that are appropriate for a given management application." The definition of the term elaborates that "The NRV is a tool for assessing the ecological integrity and does not necessarily constitute a management target or desired condition" (FSM 2020.5, citing the planning handbook at FSH 1909.12, zero code, section 05). Consequently, management actions that are consistent with the inherent capability of the plan area are the best approach to restoring ecological integrity.

Specific Comments on the Proposed Policy

Comment: One commenter stated that contemporary ecology has abandoned the concept of NRV due to the arbitrary nature of agreeing on a time scale, or due to the implied exclusion of historic burning by Native Americans, and added that ecologists have advocated the term HRV (historic range of variability). Another commenter stated that the term "Ecological Integrity" is misleading by indiscriminately implying that "species composition can withstand and recover from most perturbations imposed by natural environmental dynamics or human influence" and adds, as an example, that this definition seems to have no coherent relevance to species whose survival has depended on burning by Native Americans.

Response: The final policy retains the concept of NRV. The time period used in the definition for natural range of variation is pre-European, and, therefore, includes historic burning by Native Americans. Therefore, this policy would apply to the restoration of species that were dependent on burning by the Native Americans.

Comment: The definition for ecosystem includes basic ecological functions such as hydrological and nutrient cycling. The definition should also include "capture, storage, and release of water and nutrients." It could be argued that "nutrient cycling" includes all these processes, but our concern arises because both old growth forest and young plantation cycle nutrients, but there is a big and important difference between the nutrient capital stored in each. Restoration should include recovery of lost capital. In addition, if "function" and "process" are to be used synonymously, then "growth and mortality" should be added to the definition of ecosystem.

Response: The suggested text to add capture, storage, and release of water and nutrients to hydrological and nutrient cycling to differentiate between old growth forests and young plantations was not adopted in the final policy. Ecological restoration focuses on reestablishing the composition, structure, pattern, and ecological processes necessary to facilitate terrestrial and aquatic ecosystem sustainability, resilience, and health under current and future conditions. The primary objective of restoration is to place the ecosystem along an ecological trajectory that is sustainable.

The recommendation to add "growth and mortality" was not adopted. Although they are important processes, they are sub-processes of energy flow and would not be at the same relative level as the basic ecological functions of energy flow, nutrient cycling and retention, soil development and retention, predation and herbivory, and natural disturbances.

Comment: One respondent wanted to add a definition of ecological composition to the list of definitions at FSM 2020.5 because composition is a critical component of ecological function, structure, and process.

Response: The definition of ecosystem, in the planning rule and planning handbook, at FSH 1909.12, zero code, secion 05, includes and explains the concept of composition. The addition of a separate definition for ecological composition is, therefore, unnecessary.

Comment: Revise the definition of "Ecological Integrity" to eliminate the requirement to manage within the NRV.

Response: The definition of "ecological integrity" was not changed in the final policy. There is no requirement to manage within the NRV. The NRV is a tool for assessing ecological integrity and does not necessarily constitute a management target or desired condition (FSM 2020.5, citing the planning handbook at FSH 19012.12, zero code, section 05).

Comment: Respondents were concerned that restoration and ecological sustainability were being placed above other forest uses and that all the activities on national forests will be required to have a restoration objective.

Response: The final policy has been clarified to state that not all activities on National Forest System lands are required to have a restoration objective.

Comment: FSM 2020.3(6) omits requirements for consultation with State and local government entities.

Response: There is no statutory, regulatory, or policy requirement to consult with State and local government entities, but the expectation to engage with State and local governments has been added to FSM 2020.3(6).

Comment: The objectives fail to acknowledge the mandates of the Multiple-Use Sustained-Yield Act and the National Forest Management Act of 1976.

Response: Restoration is accomplished to ensure that resources are usable and sustainable into perpetuity; consequently this policy is wholly compatible with the Multiple-Use and Sustained-Yield Act and the National Forest Management Act of 1976. In addition, a statement has been added to the final policy that explicitly acknowledges that this policy must comply with all applicable laws and regulations, including the Multiple-Use and Sustained-Yield Act, the National Forest Management Act of 1976, and the principal statutes listed in FSM 2020.11.

Comment: The responsibilities of Forest Supervisors (FSM 2020.45) and District Rangers (FSM 2020.46) should be expanded to include incorporation of net restoration goals and outcomes in all forest management projects. If restoration is just one among many types of projects undertaken by District Rangers, while they also pursue non-restorative actions, there is no assurance of net progress toward restoration objectives.

Response: The final wording in the policy is unchanged. The Forest Service does not have net restoration goals and outcomes. Although restoration is a key objective for the Forest Service, there are other projects that are not restoration, such as fuels reduction treatments within the wildland urban interface. However, the Forest Supervisors and District Rangers are responsible for development and approval of projects to reestablish and retain ecological resilience of National Forest System lands and resources to achieve sustainable management and provide a broad range of ecosystem services that are consistent with regional and national policy.

Comment: The proposed policy states that restoration management activities for ecosystems should "assist in their recovery from the impacts of human uses." This statement implies that human uses should be removed to accomplish objectives.

Response: The policy statements in the final directive have been revised to provide that "restoration activities should be evaluated within the context of NRV, the potential future climate trajectories, and to counter detrimental human uses."

Comment: Respondents suggested that the Policy section (FSM 2020.3) should also promote ecosystem processes and function, biodiversity, and soils.

Response: No change to the policy is needed. Ecosystem restoration is the objective of the policy, and the definition of "ecosystem" states that it is commonly described in terms of its composition), and function, including soil development and retention (see FSM 2020.5 and the planning handbook at FSH 1909.12, zero code); consequently, the respondent's suggestions were already incorporated in the proposed as well as the final policy.

Comment: Respondents questioned the presumed link between historic system processes (implied by the use of the word "reestablish") with the processes required to support "ecosystem sustainability, resilience, and health under current and future conditions." The respondents believe there will be confusion in the implementation of the policy due to the differences in processes necessary to support historic systems and those to support current and future conditions; one example is warming conditions.

Response: The final policy includes slight modifications to include the most recent research that more fully takes into account climate change. The term *functional restoration* has been added to acknowledge that in some situations it is not possible or desirable to reestablish key ecosystem characteristics within the NRV. The policy provides the flexibility to define desired conditions under warming conditions outside the NRV, if necessary.

Comment: Another respondent found that the Objective section focuses on building resiliency, whereas the Policy section focuses on restoration.

Response: Resilience is a desired property of a restored ecosystem. The use of the terms "resilience" and "restoration" are found in the Objective section (FSM 2020.2) and the Policy section (FSM 2020.3) by design. However, a definition of the term *resilience* has been listed as available in FSH 1909.12, zero code chapter, section 05 to clarify the meaning when the term is used in the policy.

Comment: A respondent was concerned that the proposed policy did not address the causes that contribute to ecological degradation, such as grazing and fire suppression. Another respondent stated that the policy should explicitly recognize the potential conflict between restoration goals, such as fuel reduction versus biomass accumulation, and that an objective of the policy should be to harmonize conflicting goals.

Response: The purpose of this policy is to establish broad direction for reestablishing and retaining ecological resilience of National Forest System lands and associated resources to achieve sustainable management and provide a broad range of ecosystem services. It is always the case that, as the Forest Service engages in day-to-day management of units of the National Forest System, the responsible official considers potential conflicts, which may include conflicts between restoration goals.

Comment: Some respondents were concerned that the policy has the potential to limit the available areas of Forest Service land for recreation and to arbitrarily close trails to off-highway-vehicle recreation, and that the Forest Service should recognize that recreation and other multiple uses are legitimate uses on NFS lands.

Response: A statement has been added in the Policy section (FSM 2020.3) that explicitly acknowledges that this policy must comply with all applicable laws and regulations, including the Multiple-Use Sustained-Yield Act (MUSYA) and the National Forest Management Act (NFMA) of 1976, and the statutes listed in FSM 2020.11. Managing for multiple-use and sustained-yield of goods and services has often required the Forest Service to deal with several conflicting factors and uses at the same time. In some instances, restoration may indeed limit some uses. But, this policy does not mandate restoration in all situations. When and how to restore specific ecosystems will still be a case-by-case matter for the Forest Service's responsible officials who will be informed by public involvement.

Comment: The Policy section (FSM 2020.3) in the proposed policy should be rewritten to focus on creating functioning systems.

Response: The language has been changed to emphasize that goals and activities should focus on restoring the underlying processes that create functioning ecosystems where appropriate.

Comment: The following sentence should be added within the final Policy section (FSM 2020.3): "The NRV is a tool for assessing the ecological integrity and does not necessarily constitute a management target or desired condition."

Response: Although the suggested text was not added to the final Policy section it is included in the definition of the NRV (FSM 2025, citing the planning handbook at FSH 1909.12, zero code, section 05).

Comment: The policy should stress functional restoration, not ecological restoration, or it should at least provide a logical link between functional restoration and ecological restoration; functional restoration should be defined in the policy.

Response: In the final directive, functional restoration has been added to the Policy (FSM 2020.3) and the Definition (FSM 2020.5) sections. An explanation of its use and relationship with ecological restoration is in the "Background and Need for the Directive" section of this document.

Comment: Reversing the order of the objectives would change the tone to a more forward-looking policy.

Response: The order of the objectives (FSM 2020.2) has been changed and the objectives themselves have been clarified in the final policy.

Comment: Respondents noted that social and economic sustainability as well as ecological factors should be emphasized within the policy.

Response: Consideration for public values and desires, and the contribution to ecological, social, and economic sustainability, among other considerations, has been added to the Policy section, FSM 2020.3(3)(b).

Interim Directives

The Forest Service has been using an interim directive since 2008. Below are the major differences between the interim directive and the permanent policy:

1. The title has changed from "Ecological Restoration and Resilience" to "Ecosystem Restoration" in the final policy, to better align its title with its content (establishing that not only ecological restoration but also functional restoration are appropriate approaches) and with the mission of the Agency.
2. The final policy adopted from the 2012 Planning Rule directives (FSH 1909.12) the concepts, terms, and definitions for the following: Functional restoration, natural range of variation, adaptation, disturbance, disturbance regime, landscape, stressors, and sustainability.
3. The final policy adds to the Policy section (FSM 2020.50 a requirement to give consideration for the recovery, maintenance, enhancement, and the resilience of carbon stocks associated with National Forest System lands.
4. The final policy adds in the Policy section public values and desires; contributions to ecological, social, and economic sustainability; the natural range of variation (NRV); and ecological integrity as matters to consider in development of restoration goals or objectives.
5. The contents of the Principles section (FSM 2020.6) in the interim directive was distributed to other sections of the final policy and the Principle section was dropped.
6. The final policy adds guidance for ecological and functional restoration activities.

Regulatory Certification

Environmental Impact

This final directive establishes policy for restoring and managing ecosystems on National Forest System lands, but does not direct that any specific action be taken. Forest Service NEPA procedures at 36 CFR 220.6(d)(2) excludes from documentation in an environmental assessment or environmental impact statement "rules, regulations, or policies to establish Service-wide administrative procedures, program processes, or instructions." The Agency's conclusion is that this final directive falls within the category of actions in 36 CFR 220.6(d)(2); no extraordinary circumstances exist which would require preparation of an environmental assessment or environmental impact statement.

Regulatory Impact

This final directive has been reviewed under USDA procedures and Executive Order 12866, Regulatory Planning and Review. This is not an economically significant action. This action would not have an annual effect of $100 million or more on the economy nor adversely affect productivity, competition, jobs, the environment, public health or safety, nor State, local, or Tribal governments. This action would not interfere with an action taken or planned by another agency. This action would not alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients of such programs. However, this final directive has been designated as significant and therefore is subject to Office of Management and Budget review under Executive Order 12866.

In accordance with OMB circular A–4, "Regulatory Analysis," a cost/benefit analysis was conducted comparing the costs and benefits associated with the "no action" alternative of not having an Agency policy and the alternative of adopting the final restoration policy. Many benefits and costs associated with the final Agency policy are not quantifiable. Benefits include providing consistent and uniform understanding and Service-wide application of restoration policies, principles, and terminology; increasing Agency effectiveness when planning and implementing ecosystem management activities; and fostering better understanding and collaboration among interests from local to national levels. It is anticipated that this final directive would reduce costs by providing clear policy, definitions, and principles for restoring or modifying ecosystems, thereby reducing ad hoc or inconsistent interpretation of terminology and policy.

This final directive has been reviewed in light of the Regulatory Flexibility Act, as amended (5 U.S.C. 601 *et seq.*), and this action will not have a significant economic impact on a substantial number of small entities as defined by that Act. A threshold regulatory flexibility analysis is not required, under the Regulatory Flexibility Act, because this directive is broad Agency policy that imposes no impacts or requirements on small or large entities. This directive will increase Agency effectiveness when planning and implementing restoration activities at the local level.

Federalism

The Agency considered this final directive under requirements of Executive Order 13132, Federalism. The Agency concludes this final directive conforms to the federalism principles set out in this Executive Order; will not impose any compliance costs on the States; and will not have substantial direct effects on the States or the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, the Agency has determined that no further assessment of federalism implications is necessary.

Consultation and Coordination With Indian Tribal Governments

Pursuant to Executive Order 13175 of November 6, 2000, "Consultation and Coordination with Indian Tribal Governments," Tribes were invited to consult on the proposed directive prior to review and comment by the general public. The consultation process was initiated through written instructions from the Deputy Chief for the National Forest System to the Regional Foresters and subsequently to the Forest Supervisors. Upon request from the Tribes, formal consultation was conducted by the Forest Supervisors and/or District Rangers with assistance from staff. Tribal comments were submitted to the Washington Office staff designated as lead for this policy and were addressed in the notice of proposed directive that was published in the **Federal Register**.

Implementation of this directive primarily occurs at the local level (national forest or grassland unit) through land management and project-level planning and accomplishment. When local actions are initiated, another level of consultation would occur with Tribes at the local level where site-specific land and resource management goals and objectives are established. Also, at that level, the design and effects of management activities are most effectively addressed in relation to the Agency's tribal trust responsibilities and Indian tribal treaty rights to assure Tribal interests are respected.

This final directive establishes broad policy for reestablishing and retaining ecological resilience of National Forest System lands and resources to achieve sustainable management and provide a broad range of ecosystem services but does not directly affect the occupancy and use of National Forest System land. The Agency has assessed the impact of this final directive on Indian Tribes through tribal consultation and determined that it does not have substantial direct or unique effects on Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

The Agency has also determined this final directive does not impose substantial direct compliance costs on Indian tribal governments or preempt tribal law.

No Takings Implications

This final directive has been analyzed in accordance with the principles and criteria contained in Executive Order 12630, Governmental Actions and Interference with *Constitutionally Protected Property Rights*, and it has been determined this final directive does not pose the risk of a taking of protected private property.

Civil Justice Reform

This final directive has been reviewed under Executive Order 12988 "Civil Justice Reform." After adoption of the final directive, (1) all State and local laws and regulations that conflict with this final directive or that would impede full implementation of this directive would be preempted; (2) no retroactive effect would be given to this final directive; and (3) this final directive would not require the use of administrative proceedings before parties could file suit in court challenging its provisions.

Unfunded Mandates

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), signed into law on March 22, 1995, the Agency assessed the effects of this final directive on State, local, and tribal governments and the private sector. This final directive does not compel the annual expenditure of $100 million or more by any State, local, or tribal government in the aggregate or by anyone in the private sector. Therefore, a statement under section 202 of the act is not required.

Energy Effects

This final directive has been reviewed under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. It has been determined this final directive does not constitute a significant energy action as defined in the Executive Order.

Controlling Paperwork Burdens on the Public

This final directive does not contain any additional record keeping or reporting requirements or other information collection requirements as defined in 5 CFR part 1320 that are not already required by law and already approved for use, and therefore imposes no additional paperwork burden on the public. Accordingly, the review provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR part 1320 do not apply.

Forest Service Manual

The Forest Service policy is established in Forest Service Manual 2020 as follows:

Chapter 2020—Ecosystem Restoration

FSM 2020 provides policy for reestablishing and retaining ecological resilience of National Forest System lands and resources to achieve sustainable multiple use management and provide a broad range of ecosystem services. Resilient ecosystems have greater capacity to survive disturbances and large-scale threats, especially under changing and uncertain future environmental conditions, such as those driven by climate change and human uses. The directive reaches across all program areas and activities applicable to management of National Forest System lands and resources so as to ensure integration and coordination at all levels and organizational units. It does not directly affect land management plans or the occupancy and use of National Forest System lands, leaving to responsible officials the discretion to decide when and how to authorize restoration projects and activities. When applying or implementing this policy, the Forest Service must comply with applicable laws and regulations, including the National Forest Management Act (NFMA), Multiple-Use Sustained-Yield Act (MUSYA), and the principal statutes in section FSM 2020.11.

2020.1—Authority

The authority for sustainably managing the National Forest System derives from laws enacted by Congress that set out the purpose for which it has been established and is to be administered. These laws are cited throughout the Forest Service Manual and Handbooks. FSM 1010 lists the most significant laws and provides guidance on where to obtain copies of them.

The history of federal policies, treaties, statutes, court decisions, and Presidential direction regarding Indian Tribes and tribal rights and interests is extensive. FSM 1563.01a through FSM 1563.01i set out the legal authorities relevant to Forest Service relationships with Tribes.

The President issued direction through several Executive Orders relevant to protection of resources or restoration of ecosystem processes and functions (FSM 2020.12). Also, numerous regulations governing the sustainable management and restoration of National Forest System lands are found in the Code of Federal Regulations under Title 36, Chapter II, parts 200–299.

2020.11—Laws

The principal statutes governing the reestablishing and retaining of the ecological resilience of National Forest System lands and resources to achieve sustainable multiple use management and provide a broad range of ecosystem services, include but are not limited to, the following statutes, which are listed in alphabetical order. Except where specifically stated, these statutes apply to all National Forest System lands and resources.

1. *Forest and Rangeland Renewable Resources Planning Act (RPA) of 1974,* as amended by *National Forest Management Act* (NFMA) of 1976 (16 U.S.C. 1600–1614, 472a). This Act states that the development and administration of the renewable resources of the National Forest System are to be in full accord with the concepts for multiple use and sustained yield of products and services as set forth in the Multiple-Use Sustained-Yield Act of 1960. The Act establishes

the policy of the Congress that all forested lands in the National Forest System be maintained in appropriate forest cover with species of trees, degree of stocking, rate of growth, and stand conditions designed to secure the maximum benefits of multiple-use, sustained-yield management in accordance with land management plans. It sets forth the requirements for land and resource management plans for units of the National Forest System, including requiring guidelines to provide for diversity of plant and animal communities based on the suitability and capability of the specific land area in order to meet overall multiple-use objectives.

2. *Healthy Forests Restoration Act (HFRA) of 2003* (16 U.S.C. 6501–6591). This Act provides processes for developing and implementing hazardous fuel reduction projects on certain types of "at-risk" National Forest System and Bureau of Land Management (BLM) lands, and also provides other authorities and direction to help reduce hazardous fuels and protect, restore, and enhance healthy forest and rangeland ecosystems.

3. *Multiple-Use Sustained-Yield Act of 1960* (16 U.S.C. 528–531). This Act states that the National Forests are to be administered for outdoor recreation, range, timber, watershed, and wildlife and fish purposes, and adds that the establishment and maintenance of wilderness areas are consistent with this Act. This Act directs the Secretary to manage renewable surface resources of the National Forests for multiple use and sustained yield of the several products and services obtained therefrom. Multiple use means the management of all the various renewable surface resources of the National Forests in the combination that will best meet the needs of the American people; providing for periodic adjustments in use to conform to changing needs and conditions; and harmonious and coordinated management of the resources without impairment of the productivity of the land. Sustained yield of the several products and services means achieving and maintaining in perpetuity a high-level annual or regular periodic output of renewable resources without impairment of the productivity of the land.

4. *Organic Administration Act* (at 16 U.S.C. 475, 551). This Act states the purpose of the National Forests, and directs their control and administration to be in accord with such purpose, that is, "[n]o national forest shall be established, except to improve and protect the forest within the boundaries, or for the purpose of securing favorable conditions of water flows, and to furnish a continuous supply of timber for the use and necessities of citizens of the United States." The Act authorizes the Secretary of Agriculture to "make such rules and regulations . . . to preserve the [national] forests from destruction."

Other statutes, regulations, and Executive Orders related to the policies in the restoration policy are referenced in FSM 2020.6.

2020.2—Objective

Ecosystems ecologically or functionally restored, so that over the long term they are resilient and can be managed for multiple use and provide ecosystem services, including but not limited to carbon storage and sequestration.

2020.3—Policy

1. The Forest Service will emphasize ecosystem restoration across the National Forest System and within its multiple use mandate.

2. The Forest Service land and resource management plans, project plans, and other Forest Service activities may include goals or objectives for restoration. The goals or objectives for ecosystem restoration must be consistent to all applicable laws and regulations. In development of restoration goals or objectives, the Forest Service should consider:

a. Factors such as the following:

(1) Public values and desires;

(2) the natural range of variation (NRV);

(3) ecological integrity;

(4) current and likely future ecological capabilities;

(5) a range of climate and other environmental change projections;

(6) the best available scientific information; and,

(7) detrimental human uses.

b. technical and economic feasibility to achieve desired future conditions.

c. ecological, social, and economic sustainability.

d. the recovery, maintenance, and enhancement of carbon stocks.

e. opporunities to incorporate restoration objectives into resource management projects to achieve complementary or synergistic results.

f. the concept that an ecological system is dynamic and follows an ecological trajectory

g. the social, economic and ecological influences of restoration activities at multiple scales.

3. The Forest Service may reestablish, maintain, or modify the composition, structure, function, and connectivity of aquatic and terrestrial ecosystems in order to sustain their resilience and adaptive capacity.

4. Activities with localized, short-term adverse effects may be acceptable in order to achieve long-term restoration objectives.

5. The definitions for following terms in this policy are identical to the definitions for the same terms in the National Forest System, Land Management Planning Directive: adaptation, adaptive capacity, adaptive management, disturbance, disturbance regime, ecological integrity, ecosystem, ecosystem services, landscape, natural range of variation (NRV), resilience, restoration–ecological, restoration–functional, stressors, and sustainability. (FSH 1909.12, zero code, section 05).

6. When ecosystems have been altered to such an extent that reestablishing key ecosystem characteristics within the NRV may not be ecologically or economically possible, the restoration focus should be to create functioning ecosystems.

7. Resource managers should consider ecological conditions across ownerships and jurisdictions to develop and achieve landscape restoration objectives by engaging the public, State and local governments, and consultation with Indian Tribes.

8. Not all natural resource management activities are required to include restoration, and not all National Forest System lands require restoration.

2020.4—Responsibility

The responsible officials to carry out the Ecosystem Restoration Policy are the Agency employees who have the delegated authority to approve land and resource management plans, project plans, or other Forest Service activities.

2020.5—Definitions

The definitions at the Land Management Planning Handbook, FSH 1909.12, zero code chapter, section 05 at *http://www.fs.fed.us/im/directives/fsh/1909.12/wo_1909.12_zero_code.docx* apply for the following terms in this policy: Adaptation, adaptive capacity, adaptive management, carbon pool, carbon stocks, disturbance, disturbance regime, ecological integrity, ecosystem, ecosystem services, landscape, natural range of variation (NRV), resilience, restoration–ecological, restoration–functional, stressors, and sustainability.

2020.6—References

This section displays references to statutes, regulations, and Executive Orders related to the policies in FSM 2020.

2020.61—References to Statutes

1. Text of the *Agricultural Act of 2014* (16 U.S.C. 6591c and 16 U.S.C. 2113a) Title VIII, Sections 8205 & 8206 is available at: *http://www.gpo.gov/fdsys/pkg/USCODE-2014-title16/pdf/USCODE-2014-title16-chap84-subchapVI-sec6591c.pdf* and *http://www.gpo.gov/fdsys/pkg/USCODE-2014-title16/pdf/USCODE-2014-title16-chap41-sec2113a.pdf.*
2. Text of the *Anderson-Mansfield Reforestation and Revegetation Joint Resolution Act of 1949* (at 16 U.S.C. 581j and 581j (note)) is available at: *http://www.gpo.gov/fdsys/pkg/USCODE-2011-title16/pdf/USCODE-2011-title16-chap3-subchapII-sec581j.pdf.*
3. Text about visibility protection for Federal class I areas (43 U.S.C. 7491) and text about control of air pollution from Federal facilities under the *Clean Air Act (42 U.S.C. 7401, 7418, 7470. 7472, 7474, 7475, 7491, 7506, 7602)* is available at: *http://www.gpo.gov/fdsys/pkg/USCODE-2014-title42/pdf/USCODE-2014-title42-chap85-subchapI-partC-subpartii-sec7491.pdf and http://www.gpo.gov/fdsys/pkg/USCODE-2014-title42/pdf/USCODE-2014-title42-chap85-subchapI-partA-sec7418.pdf.*
4. Text about Federal facilities water pollution control responsibilities (33 U.S.C. 1323) under the *Clean Water Act* (33 U.S.C. 1251, 1254, 1323, 1324, 1329, 1342, 1344) is available at: *http://www.gpo.gov/fdsys/pkg/USCODE-2014-title33/pdf/USCODE-2014-title33-chap26-subchapIII-sec1323.pdf.*
5. Text of the *Endangered Species Act of 1973* (16 U.S.C. 1531–1544, as amended) is available at: *http://www.gpo.gov/fdsys/pkg/USCODE-2011-title16/pdf/USCODE-2011-title16-chap35.pdf.*
6. Text of the *Forest and Rangeland Renewable Resources Planning Act (RPA) of 1974,* as amended by *National Forest Management Act* (NFMA) of 1976 (16 U.S.C. 1600–1614, 472a) is available at: *http://www.gpo.gov/fdsys/pkg/USCODE-2010-title16/html/USCODE-2010-title16-chap5C.html.*
7. Text of the *Granger-Thye Act* (16 U.S.C. at 580g–h) is available at: *http://www.gpo.gov/fdsys/pkg/USCODE-2011-title16/pdf/USCODE-2011-title16-chap3-subchapI-sec580g.pdf* and *http://www.gpo.gov/fdsys/pkg/USCODE-2011-title16/pdf/USCODE-2011-title16-chap3-subchapI-sec580h.pdf.*
8. Text of the *Healthy Forests Restoration Act (HFRA) of 2003* (16 U.S.C. 6501–6591) is available at: *http://www.gpo.gov/fdsys/pkg/USCODE-2011-title16/pdf/USCODE-2011-title16-chap84.pdf.*
9. Text of the *Knutson-Vandenberg Act* (16 U.S.C. at 576b) is available at: *http://www.gpo.gov/fdsys/pkg/USCODE-2011-title16/pdf/USCODE-2011-title16-chap3-subchapI-sec576b.pdf.*
10. Text of the *Magnuson-Stevens Fishery Conservation and Management Act of 2006* (16 U.S.C. 1855, as amended) is available at: *http://www.gpo.gov/fdsys/pkg/USCODE-2011-title16/pdf/USCODE-2011-title16-chap38-subchapIV-sec1855.pdf.*
11. Text of the *Multiple-Use Sustained-Yield Act of 1960* (16 U.S.C. 528–531) is available at: *http://www.fs.fed.us/emc/nfma/includes/musya60.pdf.*
12. Text of the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) is available at: *http://www.gpo.gov/fdsys/pkg/USCODE-2011-title42/pdf/USCODE-2011-title42-chap55.pdf.*
13. Text of the North American Wetland Conservation Act (16 U.S.C. 4401 (note), 4401–4413, 16 U.S.C. 669b (note)). Section 9 (U.S.C. 4408) is available at: *http://www.gpo.gov/fdsys/pkg/USCODE-2011-title16/pdf/USCODE-2011-title16-chap64-sec4408.pdf.*
14. Text of the *Organic Administration Act* (at 16 U.S.C. 475, 551) is available at: *http://www.gpo.gov/fdsys/pkg/USCODE-2011-title16/pdf/USCODE-2011-title16-chap2-subchapI-sec475.pdf* and *http://www.gpo.gov/fdsys/pkg/USCODE-2011-title16/pdf/USCODE-2011-title16-chap3-subchapI-sec551.pdf.*
15. Text of the *Sikes Act* (16 U.S.C. at 670g) is available at: *http://www.gpo.gov/fdsys/pkg/USCODE-2010-title16/html/USCODE-2010-title16-chap5C.htm.*
16. Text of the *Tribal Forest Protection Act of 2004* (25 U.S.C. 3115a) is available at: *http://www.fs.fed.us/restoration/documents/stewardship/tfpa/TribalForestProtectionAct2004.pdf.*
17. Text of the *Weeks Act,* as amended (at 16 U.S.C. 515, 552) is available at: *http://www.fs.fed.us/land/staff/Documents/Weeks%20Law.pdf.*
18. Text of the *Wilderness Act* of September 3, 1964 (16 U.S.C. 1131–1136) is available at: *http://www.gpo.gov/fdsys/pkg/USCODE-2012-title16/pdf/USCODE-2012-title16-chap23.pdf.*
19. Selected text of the *Wild and Scenic Rivers Act* of October 2, 1968 (Public Law 90–572; 16 U.S.C. 1271–1287), as amended, is available at: *http://www.rivers.gov/documents/wsr-act.pdf.*

2020.62—References to Federal Regulations

1. Text of 36 CFR 219 governing land and resource management planning as amended through April 19, 2013 is available at: *http://www.gpo.gov/fdsys/pkg/CFR-2013-title36-vol2/pdf/CFR-2013-title36-vol2-part219.pdf.*

2020.63—References to Executive Orders

1. Text of Executive Order 11514 issued March 5, 1970, as amended by E.O. 11991, issued May 24, 1977. Protection and enhancement of environmental quality (35 FR 4247, March 7, 1970; 42 FR 26967, May 25, 1977) is available at: *http://www.archives.gov/federal-register/codification/executive-order/11514.html.*
2. Text of the *Executive Order 11644* issued February 8, 1972. Use of off-road vehicles on the public lands. (37 FR 2877, February 9, 1972). Amended by E.O. 11989 issued May 24, 1977 and E.O. 12608 issued September 9, 1987 is available at: *http://www.archives.gov/federal-register/codification/executive-order/11644.html.*
3. Text of the *Executive Order 11988* issued May 24, 1977. Floodplain management (42 FR 26951 (May 25, 1977)) is available at: *http://www.archives.gov/federal-register/codification/executive-order/11988.html.*
4. Text of the Executive Order 11990 issued May 24, 1977. Protection of wetlands. (42 FR 26961, May 25, 1977) is available at: *http://www.archives.gov/federal-register/codification/executive-order/11990.html.*
5. Text of the *Executive Order 13112* issued February 3, 1999. Invasive Species. (64 FR 6183 (February 8, 1999)) is available at: *http://www.gpo.gov/fdsys/pkg/FR-1999-02-08/pdf/99-3184.pdf.*
6. Text of the *Executive Order 13653* issued November 1, 2013. Preparing the United States for the Impacts of Climate Change. (78 FR 66819 (November 6, 2013)) is available at: *http://www.gpo.gov/fdsys/pkg/FR-2013-11-06/pdf/2013-26785.pdf.*

Dated: April 18, 2016.

Thomas L. Tidwell,

Chief, Forest Service.

[FR Doc. 2016–09750 Filed 4–26–16; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: Bureau of Industry and Security.

Title: BIS Program Evaluation.

Form Number(s): N/A.

OMB Control Number: 0694–0125.

Type of Request: Regular.

Burden Hours: 500 hours.

Number of Respondents: 3,000 respondents.

Average Hours per Response: 10 minutes per response.

Needs and Uses: This collection of information is necessary to obtain feedback from seminar participants. This information helps BIS determine the effectiveness of its programs and identifies areas for improvement. The gathering of performance measures on the BIS seminar program is also essential in meeting the agency's responsibilities under the Government Performance and Results Act (GPRA).

Affected Public: Businesses and other for-profit institutions.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

This information collection request may be viewed at *www.reginfo.gov.*

Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to Jasmeet Seehra, Office of Management and Budget (OMB), by email to *jseehra@omb.eop.gov,* or by fax to (202) 395–7285.

Dated: April 25, 2016.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2016–09811 Filed 4–26–16; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

On behalf of the Committee for the Implementation of Textile Agreements (CITA), the Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: Committee for the Implementation of Textile Agreements.

Title: Interim Procedures for Considering Requests from the Public for Textile and Apparel Safeguard Actions on Imports from Panama.

Form Number(s): N/A.

OMB Control Number: 0625–0274.

Type of Request: Regular submission.

Burden Hours: 24.

Number of Respondents: 6 (1 for Request; 5 for Comments).

Average Hours per Response: 4 hours for a Request; and 4 hours for each Comment.

Average Annual Cost to Public: $960.

Needs and Uses: Title III, Subtitle B, Section 321 through Section 328 of the United States-Panama Trade Promotion Agreement Implementation Act (the "Act") [Public Law 112–43] implements the textile and apparel safeguard provisions, provided for in Article 3.24 of the United States-Panama Trade Promotion Agreement (the "Agreement"). This safeguard mechanism applies when, as a result of the elimination of a customs duty under the Agreement, a Panamanian textile or apparel article is being imported into the United States in such increased quantities, in absolute terms or relative to the domestic market for that article, and under such conditions as to cause serious damage or actual threat thereof to a U.S. industry producing a like or directly competitive article. In these circumstances, Article 3.24 permits the United States to increase duties on the imported article from Panama to a level that does not exceed the lesser of the prevailing U.S. normal trade relations (NTR)/most-favored-nation (MFN) duty rate for the article or the U.S. NTR/MFN duty rate in effect on the day the Agreement entered into force.

The Statement of Administrative Action accompanying the Act provides that the Committee for the Implementation of Textile Agreements (CITA) will issue procedures for requesting such safeguard measures, for making its determinations under section 322(a) of the Act, and for providing relief under section 322(b) of the Act.

In Proclamation No. 8894 (77 FR 66507, November 5, 2012), the President delegated to CITA his authority under Subtitle B of Title III of the Act with respect to textile and apparel safeguard measures.

CITA must collect information in order to determine whether a domestic textile or apparel industry is being adversely impacted by imports of these products from Panama, thereby allowing CITA to take corrective action to protect the viability of the domestic textile or apparel industry, subject to section 322(b) of the Act.

Affected Public: Individuals or households; businesses or other for-profit organizations.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: April 25, 2016.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2016–09810 Filed 4–26–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

On behalf of the Committee for the Implementation of Textile Agreements (CITA), the Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: Committee for the Implementation of Textile Agreements.

Title: Interim Procedures for Considering Requests under the Commercial Availability Provision of the United States-Panama Trade Promotion Agreement.

Form Number(s): N/A.

OMB Control Number: 0625–0273.

Type of Request: Regular submission.

Burden Hours: 89.

Number of Respondents: 16 (10 for Requests; 3 for Responses; 3 for Rebuttals).

Average Hours per Response: 8 hours per Request; 2 hours per Response; and 1 hour per Rebuttal.

Needs and Uses: Title II, Section 203(o) of the United States-Panama Trade Promotion Agreement Implementation Act (the "Act") [Pub. L. 112–43] implements the commercial availability provision provided for in Article 3.25 of the United States-Panama Trade Promotion Agreement (the "Agreement"). The Agreement entered into force on October 31, 2012. Subject to the rules of origin in Annex 4.1 of the Agreement, and pursuant to the textile provisions of the Agreement, a fabric, yarn, or fiber produced in Panama or the United States and traded between the two countries is entitled to duty-free tariff treatment. Annex 3.25 of the Agreement also lists specific fabrics, yarns, and fibers that the two countries agreed are not available in commercial quantities in a timely manner from producers in Panama or the United States. The items listed in Annex 3.25 are commercially unavailable fabrics, yarns, and fibers. Articles containing these items are entitled to duty-free or preferential treatment despite containing inputs not produced in Panama or the United States.

The list of commercially unavailable fabrics, yarns, and fibers may be changed pursuant to the commercial availability provision in Chapter 3, Article 3.25, Paragraphs 4–6 of the Agreement. Under this provision, interested entities from Panama or the United States have the right to request that a specific fabric, yarn, or fiber be added to, or removed from, the list of commercially unavailable fabrics, yarns, and fibers in Annex 3.25 of the Agreement.

Pursuant to Chapter 3, Article 3.25, paragraph 6 of the Agreement, which requires that the President publish procedures for parties to exercise the right to make these requests, Section 203(o)(4) of the Act authorizes the President to establish procedures to modify the list of fabrics, yarns, or fibers not available in commercial quantities in a timely manner in either the United States or Panama as set out in Annex 3.25 of the Agreement. The President delegated the responsibility for publishing the procedures and administering commercial availability requests to the Committee for the Implementation of Textile Agreements ("CITA"), which issues procedures and acts on requests through the U.S. Department of Commerce, Office of Textiles and Apparel ("OTEXA") (See Proclamation No. 8894, 77 FR 66507, November 5, 2012).

The intent of the Commercial Availability Procedures is to foster the use of U.S. and regional products by implementing procedures that allow products to be placed on or removed from a product list, in a timely manner, and in a manner that is consistent with normal business practice. The procedures are intended to facilitate the transmission of requests; allow the market to indicate the availability of the supply of products that are the subject of requests; make available promptly, to interested entities and the public, information regarding the requests for products and offers received for those products; ensure wide participation by interested entities and parties; allow for careful review and consideration of information provided to substantiate requests and responses; and provide timely public dissemination of information used by CITA in making commercial availability determinations.

CITA must collect certain information about fabric, yarn, or fiber technical specifications and the production capabilities of Panamanian and U.S. textile producers to determine whether certain fabrics, yarns, or fibers are available in commercial quantities in a timely manner in the United States or Panama, subject to Section 203(o) of the Act.

Affected Public: Business or other for-profit.

Frequency: Varies.

Respondent's Obligation: Voluntary.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: April 25, 2016.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2016–09809 Filed 4–26–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Evaluation of State Coastal Management Program

AGENCY: Office for Coastal Management (OCM), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA), Office for Coastal Management will hold a public meeting to solicit comments for the performance evaluation of the New Jersey Coastal Management Program.

DATES: The public meeting will be held on Thursday, June 9, 2016, and written comments must be received on or before June 24, 2016. For specific date, time, and location of the public meeting see **SUPPLEMENTARY INFORMATION.**

ADDRESSES: You may submit comments on the coastal program NOAA intends to evaluate by any of the following methods:

Public Meeting and Oral Comments: A public meeting will be hold in Tuckerton, New Jersey. For specific locations, see **SUPPLEMENTARY INFORMATION.**

Written Comments: Please direct written comments to Carrie Hall Evaluator, Planning and Performance Measurement Program, Office for Coastal Management, NOS/NOAA, 1305 East-West Highway, 11th Floor, N/OCM1, Silver Spring, Maryland 20910, or *Carrie.Hall@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Carrie Hall, Evaluator, Planning and Performance Measurement Program, Office for Coastal Management, NOS/NOAA, 1305 East-West Highway, 11th Floor, N/OCM1, Silver Spring, Maryland 20910, or *Carrie.Hall@noaa.gov.*

Copies of the final evaluation findings and related material (including past performance reports and notices prepared by NOAA's Office for Coastal Management) may be obtained upon written request by contacting the person identified under **FOR FURTHER INFORMATION CONTACT.** Copies of the final evaluation findings may also be downloaded or viewed on the Internet at *https://coast.noaa.gov/czm/evaluations/evaluation_findings/index.html.*

SUPPLEMENTARY INFORMATION: Section 312 and 315 of the Coastal Zone Management Act (CZMA) require NOAA to conduct periodic evaluations of federally approved state and territorial coastal programs and national estuarine research reserves. The process includes a public meeting, consideration of written public comments and consultations with interested Federal, state, and local agencies and members of the public. During the evaluation, NOAA will consider the extent to which the state has met the national objectives, adhered to the final management plan approved by the Secretary of Commerce, and adhered to the terms of financial assistance under the CZMA. When the evaluation is completed, NOAA's Office for Coastal Management will place a notice in the **Federal Register** announcing the availability of the Final Evaluation Findings.

Specific information on the periodic evaluation of the state and territorial coastal programs and reserves that are the subject of this notice are detailed below as follows:

New Jersey Coastal Management Program Evaluation

You may participate or submit oral comments at the public meeting scheduled as follows:

Date: June 9, 2016.

Time: 5:00 p.m. local time.

Location: Jacques Cousteau National Estuarine Research Reserve, Jacques Cousteau Coastal Educational Center, 130 Great Bay Blvd., Tuckerton, New Jersey 08087.

Written public comments must be received on or before June 24, 2016.

Federal Domestic Assistance Catalog 11.419.

Coastal Zone Management Program Administration.

Dated: April 12, 2016.

John King,

Deputy Director, Office for Coastal Management, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2016–09805 Filed 4–26–16; 8:45 am]

BILLING CODE 3510–08–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE374

Marine Fisheries Advisory Committee; Charter Renewal

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of renewed charter.

SUMMARY: Notice is hereby given of the 2 year renewed charter for the Marine Fisheries Advisory Committee (MAFAC), signed on April 14, 2016.

FOR FURTHER INFORMATION CONTACT: Jennifer Lukens, Federal Program Officer, MAFAC, 301–427–8041.

SUPPLEMENTARY INFORMATION: As required by Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1982), notice is hereby given of the renewed charter for MAFAC. MAFAC was established by the Secretary of Commerce (Secretary) on February 17, 1972, to advise the Secretary on all living marine resource matters that are the responsibility of the Department of Commerce. This Committee advises and reviews the adequacy of living marine resources policies and programs to meet the needs of commercial and recreational fisheries, aquaculture, and environmental, consumer, academic, State, tribal, and other national interests. The Committee's charter must be renewed every 2 years from the date of the last renewal. The charter can be accessed on line at *www.nmfs.noaa.gov/ocs/mafac.*

Dated: April 21, 2016.

Jennifer Lukens,

Federal Program Officer, Marine Fisheries Advisory Committee.

[FR Doc. 2016–09866 Filed 4–26–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE578

Endangered and Threatened Species; Take of Anadromous Fish

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

ACTION: Notice of final determination and discussion of underlying biological analysis; notice of availability of a Record of Decision.

SUMMARY: NMFS has evaluated the joint resource management plans (RMPs) submitted to NMFS by the Washington Department of Fish and Wildlife, and the Jamestown S'Klallam Tribe, Lummi Nation, Nooksack Tribe, Stillaguamish Tribe of Indians, and Tulalip Tribes, pursuant to the limitation on take prohibitions for actions conducted under Limit 6 of the 4(d) Rule for salmon and steelhead promulgated under the Endangered Species Act (ESA). The RMPs specify the propagation of early winter steelhead to support recreational and tribal fishing in the Dungeness, Nooksack, Stillaguamish, Skykomish, and Snoqualmie River watersheds of Washington State. This document serves to notify the public that NMFS, by delegated authority from the Secretary of Commerce, has determined pursuant to Limit 6 of the 4(d) rule for salmon and steelhead that implementing and enforcing the RMPs will not appreciably reduce the likelihood of survival and recovery of Puget Sound Chinook salmon, Hood Canal summer-run chum salmon, and Puget Sound steelhead. In compliance with the National Environmental Policy Act (NEPA), NMFS also announces the availability of its Record of Decision (ROD) on its Final Environmental Impact Statement (FEIS) for the five early-winter steelhead hatchery programs in Puget Sound.

DATES: The final determination on the take limit under the ESA was made on April 15, 2016. The Record of Decision under NEPA was signed on April 15, 2016.

ADDRESSES: Written responses to the determinations should be sent to the Sustainable Fisheries Division, 1201 NE. Lloyd Boulevard, Suite 1100, Portland, OR 97232. The complete text of the determinations, the analysis of the effects of the plans, and the ROD, along with additional documents and information, are available on the NMFS West Coast Region Web site at *http://www.westcoast.fisheries.noaa.gov/hatcheries/salmon_and_steelhead_hatcheries.html.*

FOR FURTHER INFORMATION CONTACT: For ESA determinations, contact Tim Tynan at (360) 753–9579 or via email: *tim.tynan@noaa.gov.* For information on the ROD, contact Steve Leider at (360) 753–4650 or via email: *steve.leider@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Species Covered in This Notice

Chinook salmon (*Oncorhynchus tshawytscha*): Threatened, Puget Sound, naturally produced and artificially propagated.

Chum salmon (*O. keta*): Threatened, Hood Canal summer-run, naturally produced and artificially propagated.

Steelhead (*O. mykiss*): Threatened, Puget Sound, naturally produced and artificially propagated.

Background

The RMPs are represented by five Hatchery and Genetics Management Plans (HGMPs). The HGMPs describe hatchery operations intended to produce early winter steelhead to mitigate for impacts on tribal and recreational fishing caused by past and on-going human developmental activities in the Dungeness, Nooksack, Stillaguamish, Skykomish, and Snoqualmie River watersheds. They would be implemented to provide hatchery fish to: (1) Meet regional recreational fisheries objectives for the citizens of Washington State, and (2) meet tribal fishery harvest allocations that are guaranteed through treaties, as affirmed in *United States* v. *Washington* (1974). Adult steelhead produced by the programs are not intended to spawn naturally. All five proposed hatchery programs would use only hatchery fish for broodstock, and all HGMPs include monitoring and evaluation actions to assess the performance of each program, and effects on ESA-listed Puget Sound Chinook salmon, Hood Canal summer chum salmon (Dungeness River only), and Puget Sound steelhead. NMFS has determined that implementing and enforcing the RMPs will not appreciably reduce the likelihood of survival and recovery of ESA-listed Puget Sound Chinook salmon, Hood Canal summer-run chum salmon, or Puget Sound steelhead.

NMFS West Coast Region was the lead agency responsible for preparing an FEIS to analyze the impacts of NMFS's 4(d) determination under Limit 6 for the five early winter steelhead hatchery programs. The FEIS evaluates five alternatives, including the proposed action and a no-action alternative. The notice of availability of the FEIS was published in the **Federal Register** on March 11, 2016 (81 FR 12898).

Discussion of the Biological Analysis Underlying the ESA Determination

The proposed hatchery activities described in the RMPs are intended to provide non-ESA-listed adult steelhead for harvest in recreational and tribal fisheries in the five watersheds where the programs would operate. The RMPs provide the framework through which the State of Washington and the Tribes can jointly manage early winter steelhead hatchery, monitoring, and evaluation activities while meeting requirements specified under the ESA. The proposed action covers continued operation of the five hatchery programs to produce steelhead for harvest, while minimizing any impacts on the genetic integrity of natural steelhead populations, and ecological and demographic impacts on natural ESA-listed Chinook salmon, chum salmon, and steelhead.

All steelhead produced through the five programs are derived from broodstock native to Puget Sound but not native to the watersheds where the fish would be planted. The early-winter steelhead stock released through the programs is not included as part of the listed Puget Sound Steelhead Distinct Population Segment (DPS). Operational protocols applied through the five hatchery programs would minimize potential risks to associated listed natural-origin steelhead, Chinook salmon, and (for the Dungeness River program) summer chum salmon populations in each of the watersheds where the programs are located. Particular emphasis is placed on ensuring that returning adult hatchery early-winter steelhead do not interact to a substantial degree with natural-origin steelhead populations in natural spawning areas. Hatchery management measures are applied to reduce the risk of spatial and temporal overlap, straying, and interbreeding between early-winter steelhead and natural-origin steelhead. The five HGMPs share very low genetic effects on natural-origin steelhead—essentially no estimated hatchery fish contribution or gene flow—demonstrated by DNA sampling results and other analyses of genetic introgression.

As part of the proposed hatchery programs, monitoring and evaluation would be implemented to assess their effects on ESA-listed natural-origin steelhead, Chinook salmon, and summer chum salmon, and program performance in meeting harvest augmentation objectives. The hatchery plans emphasize monitoring and evaluation of genetic effects as a key objective to validate that effects are, and will remain, low and within levels identified as posing unsubstantial risks to listed natural-origin steelhead. Information gained through monitoring and evaluation will also be used to assess whether levels for other hatchery-related program impacts on listed fish (*e.g.*, hatchery facilities, competition, and predation) are unsubstantial. The RMPs include provisions for annual reports that will assess compliance with performance standards established in the plans. Review of the RMPs and reports by NMFS, Washington State, and the Tribes will occur annually to evaluate whether assumptions regarding hatchery plan effects and analyses remain valid, and whether the objectives of the plans are being accomplished. NMFS' evaluation is available on the NMFS West Coast Region Web site (see **ADDRESSES**).

Summary of Comments Received in Response to the Proposed Evaluation and Pending Determination

NMFS published two notices of its proposed evaluation and pending determinations for public review and comment on March 26, 2015 (80 FR 15984), and February 23, 2016 (81 FR 8941). The proposed evaluation and pending determination was available for public review and comment for 39 days. During the public comment period, NMFS received substantive comments specifically addressing the proposed evaluation and pending determination from two non-governmental organizations. None of the comments raised issues that required changes to the RMPs, or substantive modification of the NMFS proposed evaluation and pending determination document. In response to the comments, minor revisions were made in the NMFS document to clarify language included in the hatchery plan action description and effects evaluation sections. A detailed summary of the comments and NMFS' responses is also available on the NMFS West Coast Region Web site. Based on its evaluation and recommended determination and taking into account the public comments, NMFS issued its final determination on the early-winter steelhead hatchery RMPs.

Record of Decision—FEIS on Puget Sound Early-Winter Steelhead Programs

NMFS has decided to select Alternative 5 from the FEIS. Alternative 5 was the agency's preferred alternative in the FEIS. Under the selected alternative, NMFS would make a determination that the HGMPs submitted by the co-managers, including a revised HGMP for the Skykomish early-winter steelhead program, meet requirements of the ESA 4(d) rule. The early-winter steelhead hatchery programs proposed in the Dungeness, Nooksack, Stillaguamish, Skykomish, and Snoqualmie River watersheds would be implemented as described in the submitted HGMPs. The ROD documents NMFS's decision, identifies all alternatives considered in reaching the decision, specifies the alternative considered to be environmentally preferable, and identifies and discusses relevant factors which were balanced by NMFS in making its decision.

Authority

Under section 4 of the ESA, the Secretary of Commerce is required to adopt such regulations as she deems necessary and advisable for the conservation of species listed as threatened. The ESA salmon and steelhead 4(d) rule (65 FR 42422, July 10, 2000) specifies categories of activities that contribute to the conservation of listed salmonids and sets out the criteria for such activities. The rule further provides that the prohibitions of paragraph (a) of the rule do not apply to actions undertaken in compliance with an RMP developed jointly by the State of Washington and the Tribes and determined by NMFS to be in accordance with the salmon and steelhead 4(d) rule (65 FR 42422, July 10, 2000).

We also apply this notice in accordance with the requirements of NEPA as amended (42 U.S.C. 4371 *et seq.*) and its implementing regulations (40 CFR 1500 part 1506.6), and other appropriate Federal laws and regulations, and policies and procedures of NMFS for compliance with those regulations.

Dated: April 21, 2016.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2016–09766 Filed 4–26–16; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Papahānaumokuākea Marine National Monument Permit Application and Reports for Permits (fka Northwestern Hawaiian Islands Marine National Monument)

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and

respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before June 27, 2016.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov).*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Tia Brown, (808) 397–2660 or *Tia.Brown@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for revision and extension of a currently approved information collection. There will be minor changes to the forms and instructions.

On June 15, 2006, President Bush established the Papahānaumokuākea Marine National Monument by issuing Presidential Proclamation 8031 (71 FR 36443, June 26, 2006) under the authority of the Antiquities Act (16 U.S.C. 431). The proclamation includes restrictions and prohibitions regarding activities in the monument consistent with the authority provided by the act. Specifically, the proclamation prohibits access to the monument except when passing through without interruption or as allowed under a permit issued by NOAA and the U.S. Fish and Wildlife Service (FWS). Vessels passing through the monument without interruption are required to notify NOAA and FWS upon entering into and leaving the monument. Individuals wishing to access the monument to conduct certain regulated activities must first apply for and be granted a permit issued by NOAA and FWS to certify compliance with vessel monitoring system requirements, monument regulations and best management practices. On August 29, 2006, NOAA and FWS published a final rule codifying the provisions of the proclamation (71 FR 51134).

II. Method of Collection

Respondents have a choice of either electronic or paper forms. Methods of submittal include email of electronic forms, and mail and facsimile transmission of paper forms.

III. Data

OMB Control Number: 0648–0548.

Form Number: None.

Type of Review: Regular submission (revision and extension of a currently approved information collection).

Affected Public: Individuals, not for profit institutions; Federal, State, local, government, Native Hawaiian organizations; business or other for-profit organizations.

Estimated Number of Respondents: 411.

Estimated Time per Response: Research, Conservation and Management and Education ("general" permits), 5 hours; Special Ocean Use permits, 10 hours; Native Hawaiian Practices permits, 8 hours; Recreation permits, 6 hours; modification requests and final reports, 10 hours; annual reports, 5 hours.

Estimated Total Annual Burden Hours: 1,794.

Estimated Total Annual Cost to Public: $61,783 in recordkeeping/reporting costs and vessel monitoring system installation and maintenance.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: April 23, 2016.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2016–09922 Filed 4–26–16; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Intellectual Property Education Outreach Council Survey

ACTION: Proposed collection; comment request.

SUMMARY: The United States Patent and Trademark Office (USPTO), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on the proposed information collection as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before June 27, 2016.

ADDRESSES: You may submit comments by any of the following methods:

- *Email: InformationCollection@uspto.gov.* Include "0651–00XX comment" in the subject line of the message.
- *Federal Rulemaking Portal: http://www.regulations.gov.*
- *Mail:* Marcie Lovett, Records Management Division Director, Office of the Chief Information Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Anthony Knight, Director, Office of Stakeholder Outreach, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–3687; or by email to *Anthony.Knight@uspto.gov* with "0651–00XX comment" in the subject line. Additional information about this collection is also available at *http://www.reginfo.gov* under "Information Collection Review."

SUPPLEMENTARY INFORMATION:

I. Abstract

The United States Patent and Trademark Office (USPTO) Intellectual Property Education Outreach Council is responsible for conducting training for parties external to the USPTO. The Council is conducting a new survey to gather public feedback regarding their satisfaction with USPTO lectures and other outreach efforts.

Collecting feedback will allow for the Agency to have a pulse on customer satisfaction and adjust where necessary to meet and exceed expectations. This feedback collection will provide for ongoing, collaborative, and actionable communication between the Agency and its customers and stakeholders. It also will enable the Agency to garner customer and stakeholder feedback in an efficient and timely manner, in accordance with the USPTO's commitment to improving services. The information collected from Agency customers and stakeholders will help ensure users have an opportunity to convey their experience with USPTO outreach efforts.

Improving Agency outreach efforts requires ongoing assessment. The Agency will collect, analyze, and interpret information gathered to identify strengths and weaknesses of current services. Based on feedback received, the Agency will identify changes needed to improve services. The Agency is committed to hearing feedback from its customers. If this information is not collected, then the Agency will miss opportunities to obtain vital feedback from its customers and stakeholders on ways to improve their program and services.

II. Method of Collection

Respondents can submit the information electronically by means of the internet, or in-person at the conclusion of a USPTO outreach event.

III. Data

OMB Number: 0651–00XX.

IC Instruments and Forms: There are no forms associated with this collection. The individual instruments in this collection are listed in the table below.

Type of Review: New.

Affected Public: Individuals or households, businesses or other for-profits; and not-for-profit institutions.

Estimated Number of Respondents: 10,000.

Estimated Time per Response: 5 minutes (.083 hours).

Estimated Total Annual Respondent Burden Hours: 833.33 hours.

Estimated Total Annual Respondent (Hourly) Cost Burden: $161,391.67. The USPTO expects that attorneys, paralegals and *pro se* applicants will complete these applications. The professional hourly rate for attorneys is $410, and the hourly rates for paralegals and *pro se* applicants are $141 and $30, respectively. The average of the combined respondent rate is $193.67. The time per response, estimated annual responses, and estimated annual burden associated with each instrument in this information collection is shown in the table below.

Number	Item	Estimated time for response (minutes)	Estimated annual responses	Estimated annual burden hours	Rate ($/hr)
		(a)	(b)	(a) × (b) / 60 = (c)	
1	Survey	5 (0.083 hrs)	10,000	833.33	$193.67
Total			10,000	833.33	

Estimated Total Annual (Non-hour) Respondent Cost Burden: There are no capital start-up, maintenance, postage, or recordkeeping costs associated with this information collection. Additionally, there are no filing fees associated with this collection.

IV. Request for Comments

Comments are invited on:

(a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;

(b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information;

(c) ways to enhance the quality, utility, and clarity of the information to be collected; and

(d) ways to minimize the burden of the collection of information on respondents, *e.g.*, the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: April 21, 2016.

Marcie Lovett,

Records Management Division Director, OCIO, Office of the Chief Information Officer, United States Patent and Trademark Office.

[FR Doc. 2016–09808 Filed 4–26–16; 8:45 am]

BILLING CODE 3510–16–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2012–0026]

Agency Information Collection Activities; Submission for OMB Review; Comment Request—Requirements Pertaining to Third Party Conformity Assessment Bodies

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act ("PRA") of 1995 (44 U.S.C. chapter 35), the Consumer Product Safety Commission ("Commission" or "CPSC") announces that the Commission has submitted to the Office of Management and Budget ("OMB") a request for extension of approval of a collection of information under the requirements pertaining to third party conformity assessment bodies (OMB No. 3041–0156). In the **Federal Register** of February 12, 2016 (81 FR 7511), the CPSC published a notice to announce the agency's intention to seek extension of approval of the collection of information. The Commission received no comments. Therefore, by publication of this notice, the Commission announces that CPSC has submitted to the OMB a request for extension of approval of that collection of information, without change.

DATES: Written comments on this request for extension of approval of information collection requirements should be submitted by May 27, 2016.

ADDRESSES: Submit comments about this request by email: *OIRA_submission@omb.eop.gov* or fax: 202–395–6881. Comments by mail should be sent to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the CPSC, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503. In addition, written comments that are sent to OMB also should be submitted electronically at *http://www.regulations.gov*, under Docket No. CPSC–2012–0026.

FOR FURTHER INFORMATION CONTACT: For further information contact: Robert H. Squibb, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; (301) 504–7815, or by email to: *rsquibb@cpsc.gov.*

SUPPLEMENTARY INFORMATION: CPSC has submitted the following currently approved collection of information to OMB for extension:

Title: Requirements Pertaining to Third Party Conformity Assessment Bodies.

OMB Number: 3041–0156.

Type of Review: Renewal of collection.

Frequency of Response: On occasion.

Affected Public: Third party conformity assessment bodies seeking acceptance of accreditation or continuing accreditation.

Estimated Burden:

- *New Applications From Third Party Conformity Assessment Bodies*
  - ○ We estimate approximately 40 new applications from independent third party conformity assessment bodies will be submitted per year, taking an estimated 75 minutes to complete the initial application materials, with an estimated burden of 50 hours per year.
  - ○ We estimate approximately 3 firewalled third party conformity assessment bodies will apply per year, taking an estimated 8.4 hours to complete the initial application materials, with an estimated burden of 25.2 hours per year.
  - ○ We estimate approximately 4 governmental third party conformity assessment bodies will apply per year, taking an estimated 3 hours to complete the initial application materials, with an estimated burden of 12 hours per year.
- *Third party conformity assessment bodies updating information*
  - ○ We estimate that approximately 5 third party conformity assessment bodies will take 15 minutes to update information for only those elements of information that need updating, with an estimated burden of 1.35 hours per year.
- *Third party conformity assessment bodies that subcontracts out tests*
  - ○ We estimate that approximately 27 third party conformity assessment bodies will take 7 minutes to comply with the subcontracting recordkeeping requirement for an estimated 68,769 subcontract test, with an estimated of approximately 8,023 hours per year.
- *Third party conformity assessment bodies that voluntarily withdraw*
  - ○ We estimate approximately 8 third party conformity assessment bodies will withdraw yearly, taking an estimated 30 minutes to create and submit the required documentation, with an estimated burden of 4 hours per year.
- *Third party conformity assessment bodies that are audited*
  - ○ We estimate that approximately 228 independent third party conformity assessment bodies each year will be audited, taking approximately 4 minutes to resubmit their Form 223 and accreditation certificate, with an estimated burden of 15.2 hours per year.
  - ○ We estimate that approximately 18 firewalled third party conformity assessment bodies will spend 226 minutes collecting and preparing the documentation to submit for an audit, with estimated burden of about 68 hours per year.
  - ○ We estimate approximately 25 governmental third party conformity assessment bodies will spend 1 hour collecting and preparing the documentation to submit for an audit, with estimated burden of 25 hours per year.
- *Total Annual Burden*

Adding all of the annual estimated burden hours results in a total of 8,224 hours for third party conformity assessment bodies per year. At $38.78 per hour, the total cost of the recordkeeping associated with the Requirements Pertaining to Third Party Conformity Assessment Bodies is approximately $318,927 (8,224 hours × $38.78 = $318,927).

General Description of Collection: On March 12, 2013, the Commission issued a rule Pertaining to Third Party Conformity Assessment Bodies (78 FR 15836). The rule established the general requirements concerning third party conformity assessment bodies, such as the requirements and procedures for CPSC acceptance of the accreditation of a third party conformity assessment body, and prescribed adverse actions that may be imposed against CPSC-accepted third party conformity assessment bodies. The rule also amended the audit requirements for third party conformity assessment bodies and amends the Commission's regulation on inspections.

Dated: April 21, 2016.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2016–09711 Filed 4–26–16; 8:45 am]

BILLING CODE 6355–01–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Information Collection; Submission for OMB Review, Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (CNCS) has submitted a public information collection request (ICR) entitled AmeriCorps NCCC's Sponsor Survey for review and approval in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, (44 U.S.C. Chapter 35). Copies of this ICR, with applicable supporting documentation, may be obtained by calling the Corporation for National and Community Service, Barbara Lane, at 202–606–6867 or email to *blane@cns.gov.* Individuals who use a telecommunications device for the deaf (TTY–TDD) may call 1–800–833–3722 between 8:00 a.m. and 8:00 p.m. Eastern Time, Monday through Friday.

DATES: Comments may be submitted, identified by the title of the information collection activity, within May 27, 2016.

ADDRESSES: Comments may be submitted, identified by the title of the information collection activity, to the Office of Information and Regulatory Affairs, Attn: Ms. Sharon Mar, OMB Desk Officer for the Corporation for National and Community Service, by any of the following two methods within 30 days from the date of publication in the **Federal Register**:

(1) *By fax to:* 202–395–6974, Attention: Ms. Sharon Mar, OMB Desk Officer for the Corporation for National and Community Service; or

(2) *By email to: smar@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of CNCS, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Propose ways to enhance the quality, utility, and clarity of the information to be collected; and
- Propose ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments

A 60-day Notice requesting public comment was published in the **Federal Register** on December 28, 2105, at Volume 80 FR 80755–80756. This comment period ended February 26, 2016. No public comments were received from this Notice.

Description: This National Civilian Community Corps Sponsor Survey originally developed this Sponsor Survey to evaluate the program's performance impact on sponsoring organizations and communities. This measurement instrument works to capture outputs and outcomes of the NCCC program on the organizations and communities it serves. Completion of this information collection is not required to be considered for or obtain grant or resource funding support from AmeriCorps NCCC. CNCS also seeks to continue using the current survey until the revised survey is approved by OMB. The current application is due to expire on 8/31/2017.

Type of Review: Renewal.

Agency: Corporation for National and Community Service.

Title: NCCC Sponsor Survey.

OMB Number: 3045–0138.

Agency Number: None.

Affected Public: The NCCC sponsor survey will be administered to the project sponsor for any NCCC service project. These sponsors apply to receive a NCCC team, typically made up of 8–12 Members, for a period of approximately six-eight weeks to implement local service projects. There are approximately 1,200 projects that NCCC perform each year. The project sponsors are uniquely able to provide the information sought in the NCCC Sponsor Survey.

Total Respondents: Based on the number of projects completed last fiscal year, NCCC expects to administer 2,400 surveys each fiscal year. These may not be unique responders as many sponsors receive teams on a rotating basis and thus may complete the survey more than once per year.

Frequency: Biweekly. Each sponsor will complete only one survey per team per project.

Average Time per Response: 30 minutes.

Estimated Total Burden Hours: 1,200 hours.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintenance): None.

Dated: April 21, 2016.

Jacob Sgambati,

NCCC Director of Operations.

[FR Doc. 2016–09813 Filed 4–26–16; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Charter Renewal of Department of Defense Federal Advisory Committees

AGENCY: Department of Defense.

ACTION: Renewal of Federal Advisory Committee.

SUMMARY: The Department of Defense (DoD) is publishing this notice to announce that it is renewing the charter for the United States Strategic Command Strategic Advisory Group (“the Group”).

FOR FURTHER INFORMATION CONTACT: Jim Freeman, Advisory Committee Management Officer for the Department of Defense, 703–692–5952.

SUPPLEMENTARY INFORMATION: The Group's charter is being renewed in accordance with the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended) and 41 CFR 102–3.50(d). The Group's charter and contact information for the Board's Designated Federal Officer (DFO) can be found at *http://www.facadatabase.gov/*.

The Group provides the Secretary of Defense and the Deputy Secretary of Defense, through the Chairman of the Joint Chiefs of Staff and the Commander of the United States Strategic Command (USSTRATCOM), with independent advice and recommendations on: (a) Scientific, technical, intelligence, and policy-related matters of interest to the Joint Chiefs of Staff and the USSTRATCOM concerning the development and implementation of the Nation's strategic war plans; (b) Enhancements in USSTRATCOM's mission area responsibilities; and (c) Other matters related to the Nation's strategic forces, as requested by the Chairman of the Joint Chiefs of Staff or the Commander, USSTRATCOM.

The Board is composed of no more than 20 members who are eminent authorities in the fields of strategic policy formulation; nuclear weapon design; national command, control, communications, intelligence, and information operations; or other important aspects of the Nation's strategic forces. All members of the Group are appointed to provide advice on behalf of the Government on the basis of their best judgment without representing any particular point of view and in a manner that is free from conflict of interest. Except for reimbursement of official Group-related travel and per diem, Group members serve without compensation. The DoD, when necessary and consistent with the Group's mission and DoD policies and procedures, may establish subcommittees, task forces, or working groups to support the Board. Currently, the Chairman of the Joint Chiefs of Staff has approved one permanent subcommittee to the Group, the Stockpile Assessment Team (“the Team”). The Team is composed of no more than 15 members who are eminent authorities in the fields of strategic policy formulation; nuclear weapon design; national command, control, communications, intelligence, and information operations; or other important aspects of the Nation's strategic forces. The public or interested organizations may submit written statements to Group membership about the Group's mission and functions. Written statements may be submitted at any time or in response to the stated agenda of planned meeting of the Group. All written statements shall be submitted to the DFO for the Group, and this individual will ensure that the written statements are provided to the membership for their consideration.

Dated: April 21, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–09736 Filed 4–26–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2016–OS–0044]

Privacy Act of 1974; System of Records; Correction

AGENCY: Office of the Secretary of Defense, DoD.

ACTION: Notice to amend a System of Records; correction.

SUMMARY: On Wednesday, April 20, 2016 (81 FR 23279–23280), the Department of Defense published a notice titled Privacy Act of 1974; System of Records. Subsequent to the publication of the notice, DoD discovered an error in the **SUPPLEMENTARY INFORMATION** section. This notice corrects the error.

DATES: This correction is effective on April 27, 2016.

FOR FURTHER INFORMATION CONTACT: Aaron Siegel, 571–372–0488.

SUPPLEMENTARY INFORMATION: On page 23279, in the third column, in the **SUPPLEMENTARY INFORMATION** section, the sentence “The proposed deletion is not within the purview of subsection (r) of the Privacy Act of 1974 (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report” should read “The proposed amendment is not within the purview of subsection (r) of the Privacy Act of 1974 (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.”

Dated: April 21, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–09712 Filed 4–26–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

National Assessment Governing Board Quarterly Board Meeting

AGENCY: National Assessment Governing Board, U.S. Department of Education.

ACTION: Announcement of open and closed meetings.

SUMMARY: This notice sets forth the agenda for the May 12–14, 2016 Quarterly Meeting of the National Assessment Governing Board (hereafter referred to as Governing Board). This notice provides information to members of the public who may be interested in attending the meeting or providing written comments on the meeting. The notice of this meeting is required under § 10(a)(2) of the Federal Advisory Committee Act (FACA).

DATES: The Quarterly Board meeting will be held on the following dates:

- May 12, 2016 from 8:30 a.m. to 6:00 p.m.
- May 13, 2016 from 8:30 a.m. to 5:00 p.m.
- May 14, 2016 from 7:30 a.m. to 12:00 p.m.

ADDRESSES: Marriott Tysons Corner, 8028 Leesburg Pike, Vienna, VA 22182.

FOR FURTHER INFORMATION CONTACT: Munira Mwalimu, Executive Officer/Designated Federal Official, 800 North Capitol Street NW., Suite 825, Washington, DC 20002, telephone: (202) 357–6938, fax: (202) 357–6945.

SUPPLEMENTARY INFORMATION:

Statutory Authority and Function: The National Assessment Governing Board is established under Title III—National Assessment of Educational Progress Authorization Act, Public Law 107–279. Information on the Board and its work can be found at *www.nagb.gov.*

The Board is established to formulate policy for the National Assessment of Educational Progress (NAEP). The Board's responsibilities include the following: Selecting subject areas to be assessed, developing assessment frameworks and specifications, developing appropriate student achievement levels for each grade and subject tested, developing standards and procedures for interstate and national comparisons, improving the form and use of NAEP, developing guidelines for reporting and disseminating results, and releasing initial NAEP results to the public.

May 12–15, 2016 Committee Meetings

The Board's standing committees will meet to conduct regularly scheduled work, based on agenda items planned for this quarterly Board meeting, and follow-up items as reported in the Board's committee meeting minutes available at *http://nagb.gov/what-we-do/board-committee-reports-and-agendas.html.*

Detailed Meeting Agenda: May 12–15, 2016

May 12: Assessment Development Committee: Closed Session: 8:30 a.m.–4:00 p.m.
May 12: Executive Committee: Open Session: 4:30 p.m.–6:00 p.m.
May 13: Full Board Meeting:
Full Board: Open Session: 8:30 a.m.–10:00 a.m.; Closed Session: 12:30 p.m.–2:00 p.m.; Open Session 2:30 p.m.–5:00 p.m.

May 13: Committee Meetings

Assessment Development Committee (ADC): Open Session: 10:00 a.m.–10:40 a.m.; Closed Session: 10:45 a.m.–12:15 p.m.
Reporting and Dissemination Committee (R&D): Open Session 10:00 a.m.–12:15 p.m.
Committee on Standards, Design and Methodology (COSDAM): Open Session: 10:00 a.m.–12:15 p.m.

May 14: Full Board and Committee Meetings

Nominations Committee: Closed Session: 7:30 a.m.–8:15 a.m.
Full Board: Open Session: 8:30 a.m.–12:00 p.m.

On May 12, 2016, the Assessment Development Committee will meet in closed session from 8:30 a.m.–4:00 p.m. to review secure test items for U.S. history, civics, geography at grade 8 for the 2018 operational assessment; reading at grades 4, 8, 12 for the 2019 pilot assessment; and mathematics at grades 4 and 8 for the 2019 pilot assessment. This meeting must be conducted in closed session because the test items are secure and have not been released to the public. Public disclosure of the secure test items would significantly impede implementation of the NAEP assessment program if conducted in open session. Such matters are protected by exemption 9(B) of § 552b(c) of Title 5 U.S.C.

Thereafter, on May 12, the Executive Committee will convene in open session from 4:30 p.m. to 6:00 p.m. to conduct regularly scheduled work.

On May 13, the Full Board will meet in open session from 8:30 a.m. to 10:00 a.m. The Board will review and approve the May 12–15, 2016 Board meeting agenda and meeting minutes from the March 2016 Quarterly Board meeting. This session will be followed by a report from the Executive Director of the Governing Board, William Bushaw, followed by an update on the work of the Institute of Education Sciences (IES) provided by Ruth Neild, Deputy Director for Policy and Research, IES. The National Center for Education Statistics (NCES) update will be provided by the Acting Commissioner of NCES, Peggy Carr. The Board will recess for committee meetings at 9:45 a.m. which are scheduled to take place from 10:00 a.m. to 12:15 p.m.

The Committee on Standards, Design and Methodology and the Reporting and Dissemination (R&D) Committee will meet in open session from 10:00 a.m. to 12:15 p.m.

The Assessment Development Committee (ADC) will meet in open session from 10:00 a.m. to 10:40 a.m., and thereafter in closed session from 10:45 a.m. to 12:15 p.m. During the closed session the ADC will continue its review of secure NAEP reading test questions in grades 4, 8, and 12 for the 2019 pilot assessment and mathematics test questions at grades 4 and 8 for the 2019 pilot assessment. These test questions have not been released to the public. Disclosure of the secure NAEP items would significantly impede implementation of the NAEP assessment program if conducted in open session. Such matters are protected by exemption 9(B) of § 552b(c) of Title 5 U.S.C.

The Committee on Standards, Design and Methodology (COSDAM) will meet in open session from 10:00 a.m. to 12:15 p.m.

Following the committee meetings, on May 13, the full Board will meet in closed session from 12:30 p.m. to 2:00 p.m. to receive a briefing and discuss the 2015 NAEP Science Report Card. Results from the science assessment—national results at grades 4, 8, and 12 and state results at grades 4 and 8 have not been released to the public. Following the science presentation, the Board will receive a briefing on the 2015 mathematics results for Puerto Rico at grades 4 and 8, which have not been released to the public. Premature disclosure of the results would significantly impede implementation of the NAEP assessment program if conducted in open session. Such matters are protected by exemption 9(B) of § 552b(c) of Title 5 U.S.C.

On May 13, from 2:30 p.m. to 3:30 p.m., the Board will meet in open session to discuss the Department of Education's STEM initiative.

This session will then be followed by an update on the Board's Strategic Plan, followed by breakout sessions convened to discuss the Strategic Plan in small groups of Board members. Members of the public are welcome to observe the breakout sessions. The May 13 session of the Board meeting will adjourn at 5:00 p.m.

On May 14, the Nominations Committee will meet in closed session from 7:30 a.m. to 8:15 a.m. The Nominations Committee will receive an update on the status of the nominations for terms beginning in October 2016. The committee will then discuss planning for the Board's annual call for nominations for Board terms beginning in October 2017. The 2017 call for nominations is scheduled to start in September 2016. The Nominations Committee's discussions pertain solely to internal personnel rules and practices of an agency and information of a personal nature where disclosure would constitute an unwarranted invasion of personal privacy. As such, the discussions are protected by exemptions 2 and 6 of § 552b(c) of Title 5 of the United States Code.

The full Board will meet in open session on May 14, from 8:30 a.m. to 9:45 a.m. to discuss the Governing Board's preparedness research program. Thereafter, from 10:00 a.m. to 10:45 a.m. the Board will receive an update on committee reports and take action on the release plan for the 2016 NAEP Science Report Card. From 11:00 a.m. to 12:00 p.m., the Board will receive briefings from each breakout session (convened on Friday to discuss the Board's Strategic Plan) and discuss next steps. The May 14, 2016 meeting is scheduled to adjourn at 12:00 p.m.

Access to Records of the Meeting: Pursuant to FACA requirements, the public may also inspect the meeting materials at *www.nagb.gov* on Thursday, May 13, 2016 by 10:00 a.m. ET. The official verbatim transcripts of the public meeting sessions will be available for public inspection no later than 30 calendar days following the meeting.

Reasonable Accommodations: The meeting site is accessible to individuals with disabilities. If you will need an auxiliary aid or service to participate in the meeting (*e.g.,* interpreting service, assistive listening device, or materials in an alternate format), notify the contact person listed in this notice at least two weeks before the scheduled meeting date. Although we will attempt to meet a request received after that date, we may not be able to make available the requested auxiliary aid or service because of insufficient time to arrange it.

Electronic Access to this Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Authority: Pub. L. 107–279, Title III—National Assessment of Educational Progress § 301.

Dated: April 22, 2016.

William J. Bushaw,

Executive Director, National Assessment Governing Board (NAGB), U. S. Department of Education.

[FR Doc. 2016–09870 Filed 4–26–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF EDUCATION

Service Contract Inventory for Fiscal Year (FY) 2015

AGENCY: Office of the Chief Financial Officer, Department of Education.

ACTION: Notice of availability—FY 2015 Service Contract Inventory.

SUMMARY: Through this notice, the Secretary announces the availability of the Department of Education's service contract inventory on its Web site, at *http://www2.ed.gov/fund/data/report/contracts/servicecontractinventoryappendix/servicecontractinventory.html.* A service contract inventory is a tool for assisting an agency in better understanding how contracted services are being used to support mission and operations and whether the contractors' skills are being utilized in an appropriate manner.

FOR FURTHER INFORMATION CONTACT: Pier Connors, U.S. Department of Education, 400 Maryland Avenue SW., Washington, DC 20202 by phone at 202–245–6919 or email at *Pier.Connors@ed.gov.*

If you use a telecommunications device for the deaf or a text telephone, call the Federal Relay Service, toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: Section 743 of Division C of the Consolidated Appropriations Act of 2010, Public Law 111–117, requires civilian agencies, other than the Department of Defense, that are required to submit an inventory in accordance with the Federal Activities Inventory Reform Act of 1998 (Pub. L. 105–270, 31 U.S.C. 501 note) to submit their inventories to the Office of Federal Procurement Policy (OFPP) in the Office of Management and Budget (OMB) by December 31, 2015. In addition, section 743 requires these agencies, which include the Department of Education, to (1) make the inventory available to the public, and (2) publish in the **Federal Register** a notice announcing that the inventory is available to the public along with the name, telephone number, and email address of an agency point of contact.

Through this notice, the Department announces the availability of its inventory on the following Web site: *http://www2.ed.gov/fund/data/report/contracts/servicecontractinventoryappendix/servicecontractinventory.html.* The point of contact for the inventory is provided under the **FOR FURTHER INFORMATION CONTACT** section in this notice.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (*e.g.,* Braille, large print, or audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT.**

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Authority: Section 743 of Division C of the Consolidated Appropriations Act of 2010, Pub. L. 111–117.

Dated: April 22, 2016.

Thomas P. Skelly,

Director of Budget Service, Delegated the Duties of the Chief Financial Officer.

[FR Doc. 2016–09879 Filed 4–26–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Agency Information Collection Reinstatement

AGENCY: U.S. Department of Energy.

ACTION: Submission for Office of Management and Budget (OMB) review; public comment request.

SUMMARY: The Department of Energy (DOE), pursuant to the Paperwork Reduction Act of 1995), intends to extend for three years, an information collection request with the Office of Management and Budget (OMB). The information collection request, Historic Preservation for Energy Efficiency Programs, was initially approved on December 1, 2010 under OMB Control No. 1910–5155 and expired on September 30, 2015. The reinstatement will allow DOE to continue data collection on the status of the Weatherization Assistance Program (WAP), the State Energy Program (SEP), and the Energy Efficiency and Conservation Block Grant (EECBG) program.

Program activities will ensure compliance with Section 106 of the National Historic Preservation Act (NHPA). Comments are invited on: (a) Whether the extended collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Comments regarding this proposed information collection must be received on or before June 27, 2016. If you anticipate difficulty in submitting comments within that period, contact the person listed below as soon as possible.

ADDRESSES: Written comments may be sent to Sallie Glaize, EE–52, U.S. Department of Energy, 1000 Independence Ave. SW., Washington, DC 20585 or by email to *sallie.glaize@ee.doe.gov.*

FOR FURTHER INFORMATION CONTACT: James Carlisle, EE–5W, U.S. Department of Energy, 1000 Independence Ave. SW., Washington, DC 20585 or by email to *James.Carlisle@ee.doe.gov.*

Additional information and reporting guidance concerning the Historic Preservation reporting requirement for the WAP, SEP, and EECBG programs are available for review at: *http://www1.eere.energy.gov/wip/historic.preservation.html.*

SUPPLEMENTARY INFORMATION: This information collection request contains: (1) OMB No.: 1910–5155; (2) Information Collection Request Title: Historic Preservation for Energy Efficiency Programs; (3) Type of Review: Reinstatement; (4) Purpose: To collect data on the status of the WAP, SEP and EECBG Program activities to ensure compliance with Section 106 of the NHPA; (5) Annual Estimated Number of Respondents: 275; (6) Annual Estimated Number of Total Responses: 275; (7) Annual Estimated Number of Burden Hours: 662; (8) Annual Estimated Reporting and Recordkeeping Cost Burden: $0.

Statutory Authority: Pub. L. 89–665.

Issued in Washington, DC on April 20, 2016.

James Carlisle,

Supervisory Policy Advisor, Weatherization and Intergovernmental Office of Energy Efficiency and Renewable Energy, U.S. Department of Energy.

[FR Doc. 2016–09834 Filed 4–26–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Paducah

AGENCY: Department of Energy (DOE)

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Paducah. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Thursday, May 19, 2016 6:00 p.m.

ADDRESSES: Barkley Centre, 111 Memorial Drive, Paducah, Kentucky 42001.

FOR FURTHER INFORMATION CONTACT: Jennifer Woodard, Deputy Designated Federal Officer, Department of Energy Paducah Site Office, Post Office Box 1410, MS–103, Paducah, Kentucky 42001, (270) 441–6825.

SUPPLEMENTARY INFORMATION: Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management and related activities.

Tentative Agenda

Board Meeting—6:00 p.m.
- Call to Order, Introductions, Review of Agenda
- Administrative Issues
- Public Comments (15 minutes)
- Adjourn

Environmental Remediation Subcommittee Meeting—7:00 p.m.
- Call to Order, Introductions, Review of Agenda

- Next Steps and Actions

- Public Comments (15 minutes)
- Adjourn

Breaks Taken as Appropriate

Public Participation: The EM SSAB, Paducah, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jennifer Woodard as soon as possible in advance of the meeting at the telephone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Jennifer Woodard at the telephone number listed above. Requests must be received as soon as possible prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments. The EM SSAB, Paducah, will hear public comments pertaining to its scope (clean-up standards and environmental restoration; waste management and disposition; stabilization and disposition of non-stockpile nuclear materials; excess facilities; future land use and long-term stewardship; risk assessment and management; and clean-up science and technology activities). Comments outside of the scope may be submitted via written statement as directed above.

Minutes: Minutes will be available by writing or calling Jennifer Woodard at the address and phone number listed above. Minutes will also be available at the following Web site: *http://www.pgdpcab.energy.gov/2016_meetings.htm.*

Issued at Washington, DC, on April 20, 2016.

LaTanya R. Butler

Deputy Committee Management Officer.

[FR Doc. 2016–09833 Filed 4–26–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Nevada

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Nevada. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register.**

DATES: Wednesday, May 18, 2016, 5:00 p.m.

ADDRESSES: Frank H. Rogers Science and Technology Building, 755 East Flamingo, Las Vegas, Nevada 89119.

FOR FURTHER INFORMATION CONTACT: Barbara Ulmer, Board Administrator, 232 Energy Way, M/S 167, North Las Vegas, Nevada 89030. Phone: (702) 630–0522; Fax (702) 295–2025 or Email: *NSSAB@nnsa.doe.gov.*

SUPPLEMENTARY INFORMATION: Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

1. Briefing and Recommendation Development for Proposed Change to Long-Term Monitoring at Closed Sites at Tonopah Test Range—Work Plan Item #2
2. Briefing and Recommendation Development for Revegetation at Corrective Action Unit 111—Work Plan Item #3
3. Recommendation Development for Radioactive Waste Acceptance Program Assessment Process—Work Plan Item #7

Public Participation: The EM SSAB, Nevada, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Barbara Ulmer at least seven days in advance of the meeting at the phone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral presentations pertaining to agenda items should contact Barbara Ulmer at the telephone number listed above. The request must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments can do so during the 15 minutes allotted for public comments.

Minutes: Minutes will be available by writing to Barbara Ulmer at the address listed above or at the following Web site: *http://nv.energy.gov/nssab/MeetingMinutes.aspx.*

Issued at Washington, DC, on April 21, 2016.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2016–09832 Filed 4–26–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

State Energy Advisory Board (STEAB)

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of open teleconference.

SUMMARY: This notice announces a teleconference call of the State Energy Advisory Board (STEAB). The Federal Advisory Committee Act (Pub. L. 92–463; 86 Stat.770) requires that public notice of these meetings be announced in the **Federal Register.**

DATES: Thursday, May 19, 2016 from 3:30 p.m. to 4:30 p.m. (EDT). To receive the call-in number and passcode, please contact the Board's Designated Federal Officer at the address or phone number listed below.

FOR FURTHER INFORMATION CONTACT: Michael Li, Policy Advisor, Office of Energy Efficiency and Renewable Energy, U.S. Department of Energy, 1000 Independence Ave. SW., Washington, DC 20585. Phone number 202–287–5718, and email: *michael.li@ee.doe.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: To make recommendations to the Assistant Secretary for the Office of Energy Efficiency and Renewable Energy regarding goals and objectives, programmatic and administrative policies, and to otherwise carry out the Board's responsibilities as designated in the State Energy Efficiency Programs Improvement Act of 1990 (Pub. L. 101–440).

Tentative Agenda: Receive STEAB Task Force updates on action items and revised objectives for FY 2016, discuss follow-up opportunities and engagement with EERE and other DOE staff as needed to keep Task Force work moving forward, continue engagement with DOE, EERE and EPSA staff regarding energy efficiency and renewable energy projects and initiatives, and receive updates on member activities within their states. Recap March meeting and follow-up on action items from that meeting.

Public Participation: The meeting is open to the public. Written statements may be filed with the Board either before or after the meeting. Members of the public who wish to make oral statements pertaining to agenda items should contact Michael Li at the address or telephone number listed above. Requests to make oral comments must be received five days prior to the meeting; reasonable provision will be made to include requested topic(s) on the agenda. The Chair of the Board is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business.

Minutes: The minutes of the meeting will be available for public review and copying within 60 days on the STEAB Web site at: *http://www.energy.gov/eere/steab/state-energy-advisory-board.*

Issued at Washington, DC, on April 20, 2016.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2016–09829 Filed 4–26–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Availability of the Draft Environmental Impact Statement for the Proposed Leach XPress Project and Rayne XPress Expansion Project

	Docket No.
Columbia Gas Transmission, LLC	CP15–514–000
Columbia Gulf Transmission, LLC	CP15–539–000

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared a draft environmental impact statement (EIS) for the Leach XPress and Rayne XPress Expansion Projects (Projects), proposed by Columbia Gas Transmission, LLC (Columbia Gas) and Columbia Gulf Transmission, LLC (Columbia Gulf), respectively, in the above-referenced dockets. Columbia Gas requests authorization to construct, operate, abandon in-place, replace, and operate certain natural gas pipeline facilities to transport about 1.5 million dekatherms of natural gas per day of firm transportation service to natural gas consumers served by the Columbia Gas pipeline systems. Columbia Gulf requests authorization to add new compression and provide about 621,000 dekatherms per day of firm transportation on Columbia Gulf's system.

The draft EIS assesses the potential environmental effects of the construction and operation of the Projects in accordance with the requirements of the National Environmental Policy Act (NEPA). The FERC staff concludes that approval of the Projects would result in limited adverse environmental impacts, with the exception of impacts on forested land; however, these impacts would be reduced to less than significant levels with the implementation of Columbia Gas' and Columbia Gulf's proposed mitigation and the additional measures recommended by staff in the draft EIS.

The U.S. Environmental Protection Agency, the U.S. Army Corps of Engineers, U.S. Fish and Wildlife Service, the Pennsylvania Department of Environmental Protection, the Pennsylvania Department of Conservation and Natural Resources, the Ohio Environmental Protection Agency, the West Virginia Department of Environmental Protection, the West Virginia Department of Natural Resources, and the Kentucky Department for Environmental Protection participated as cooperating agencies in the preparation of the EIS. Cooperating agencies have jurisdiction by law or special expertise with respect to resources potentially affected by the proposals and participate in the NEPA analysis. Although the cooperating agencies provided input to the conclusions and recommendations presented in the draft EIS, the agencies will present their own conclusions and recommendations in their respective Records of Decision for the Projects.

The draft EIS addresses the potential environmental effects of the construction and operation of the following facilities:

- 133 miles of new 30- and 36-inch-diameter natural gas pipeline, 27 miles of 36-inch-diameter looping pipeline[1] in Pennsylvania (Greene County), Ohio (Fairfield, Hocking, Monroe, Morgan, Muskingum, Noble, Perry and Vinton Counties) and West Virginia (Marshall County), 28 miles of 20-inch-diameter pipeline to be abandoned in place in Ohio (Fairfield, Hocking, and Vinton Counties), three new compressor stations, three existing compressor station modifications, four new and one modified regulator stations, 13 pig launcher and receiver facilities,[2] nine mainline valves, and four odorization facilities proposed by Columbia Gas; and
- the new Grayson Compressor Station in Carter County, Kentucky, the new Means Compressor Station in Menifee and Montgomery Counties, Kentucky, and modification of the existing Means Measurement and Regulation Station in Montgomery County, Kentucky proposed by Columbia Gulf.

The FERC staff mailed copies of the draft EIS to federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American tribes; potentially affected landowners and other interested individuals and groups; newspapers and libraries in the project area; and parties to this proceeding. Paper copy versions of this EIS were mailed to those specifically requesting them; all others received a CD version. In addition, the draft EIS is available for public viewing on the FERC's Web site (*www.ferc.gov*) using the eLibrary link. A limited number of copies are available for distribution and public inspection at: Federal Energy Regulatory Commission, Public Reference Room, 888 First Street NE., Room 2A, Washington, DC 20426, (202) 502–8371.

Any person wishing to comment on the draft EIS may do so. To ensure consideration of your comments on the proposal in the final EIS, it is important that the Commission receive your comments on or before June 13, 2016.

For your convenience, there are four methods you can use to submit your comments to the Commission. The Commission will provide equal consideration to all comments received, whether filed in written form or provided verbally. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502–8258 or *efiling@ferc.gov.* Please carefully follow these instructions so that your comments are properly recorded.

(1) You can file your comments electronically using the eComment feature on the Commission's Web site (*www.ferc.gov*) under the link to Documents and Filings. This is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the eFiling feature on the Commission's Web site (*www.ferc.gov*) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on "eRegister." If you are filing a comment on a particular project, please select "Comment on a Filing" as the filing type; or

(3) You can file a paper copy of your comments by mailing them to the following address. Be sure to reference the applicable project docket number (CP15–514–000 or CP15–539–000) with your submission: Nathaniel J. Davis, Sr., Deputy Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

(4) In lieu of sending written or electronic comments, the Commission invites you to attend one of the public comment meetings its staff will conduct in the project area to receive comments on the draft EIS, scheduled as follows:

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[1] A pipeline loop is a segment of pipe constructed parallel to an existing pipeline to increase capacity.

[2] A pig is an internal tool that can be used to clean and dry a pipeline and/or to inspect it for damage or corrosion.

Date	Location
Wednesday, May 18, 2016	Noble County Community Center, Noble County Fairgrounds, (Fairground Road), Caldwell, OH 43724, 740–509–8077.
Thursday, May 19, 2016	Grand Vue Park (Banquet Hall), 250 Trail Drive, Moundsville, WV 26041, 304–845–9810.
Tuesday, May 24, 2016	Lee's Banquet Haus, 580 Radio Lane, Logan, OH 43138, 740–603–7639.
Wednesday, May 25, 2016	Oak Hill Elementary School, 401 East Evans Street, Oak Hill, OH 45656, 740–682–7096.
Thursday, May 26, 2016	Huntington High School, 1 Highlander Way, Huntington, WV 25701, 304–528–6400.

We will begin our sign up of speakers at 5:30 p.m. The comments meetings will begin at 6:00 p.m. with a description of our environmental review process by Commission staff, after which speakers will be called. The meetings will end once all speakers have provided their comments or at 10:00 p.m., whichever comes first. The meetings will be recorded by a court reporter to ensure comments are accurately recorded. Transcripts will be entered into the formal record of the Commission proceeding.

Any person seeking to become a party to the proceeding must file a motion to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (18 CFR Part 385.214).[3] Only intervenors have the right to seek rehearing of the Commission's decision. The Commission grants affected landowners and others with environmental concerns intervenor status upon showing good cause by stating that they have a clear and direct interest in this proceeding which no other party can adequately represent. Simply filing environmental comments will not give you intervenor status, but you do not need intervenor status to have your comments considered.

Questions?

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC Web site (*www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on "General Search," and enter the docket number excluding the last three digits in the Docket Number field (*i.e.*, CP15–514 or CP15–539). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676; for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription that allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/docs-filing/esubscription.asp*.

Dated: April 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–09824 Filed 4–26–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER15–746–003.
Applicants: RC Cape May Holdings, LLC.
Description: Report Filing: April 2016 Refund Report to be effective N/A.
Filed Date: 4/21/16.
Accession Number: 20160421–5098.
Comments Due: 5 p.m. ET 5/12/16.

Docket Numbers: ER15–878–000; ER15–878–001.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.19a(b) Refund Report to be effective N/A.
Filed Date: 4/21/16.
Accession Number: 20160421–5083.
Comments Due: 5 p.m. ET 5/12/16.

Docket Numbers: ER15–1825–004.
Applicants: California Independent System Operator Corporation.
Description: Compliance filing: 2016–4–20_PetitionLtdWaiver-Request_Short_Comment_Period (ER15–1825) to be effective N/A.
Filed Date: 4/20/16.
Accession Number: 20160420–5166.
Comments Due: 5 p.m. ET 4/27/16.

Docket Numbers: ER16–438–001; ER15–2211–007; ER13–1266–006.
Applicants: Marshall Wind Energy LLC, MidAmerican Energy Services, LLC, CalEnergy, LLC.
Description: Supplement to December 18, 2015 Updated Market Power Analysis for Southwest Power Pool Region of Marshall Wind Energy LLC, et. al.
Filed Date: 4/20/16.
Accession Number: 20160420–5194.
Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: ER16–897–002.
Applicants: California Independent System Operator Corporation.
Description: Compliance filing: 2016–4–20_PetitionLtdWaiver-Request_Short_Comment_Period (ER16–897) to be effective N/A.
Filed Date: 4/20/16.
Accession Number: 20160420–5167.
Comments Due: 5 p.m. ET 4/27/16.

Docket Numbers: ER16–1076–001.
Applicants: 360Recycling.
Description: Tariff Amendment: Amended 360 Recycling MBR Filing to be effective 4/19/2016.
Filed Date: 4/21/16.
Accession Number: 20160421–5097.
Comments Due: 5 p.m. ET 5/12/16.

Docket Numbers: ER16–1482–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Amendment to WMPA SA No. 3524, Queue No. X3–066 per Assignment to Marina Energy to be effective 3/27/2013.
Filed Date: 4/21/16.
Accession Number: 20160421–5099.
Comments Due: 5 p.m. ET 5/12/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf*. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

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[3] See the previous discussion on the methods for filing comments.

Dated: April 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–09825 Filed 4–26–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP16–853–000.
Applicants: Centra Pipelines Minnesota Inc.
Description: § 4(d) Rate Filing: Updated Shipper Index April 2016 to be effective 6/1/2016.
Filed Date: 4/18/16.
Accession Number: 20160418–5125.
Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–854–000.
Applicants: Rockies Express Pipeline LLC.
Description: § 4(d) Rate Filing: Neg Rate BP 2016–04–18 to be effective 4/16/2016.
Filed Date: 4/18/16.
Accession Number: 20160418–5170.
Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–855–000.
Applicants: National Grid LNG, LLC.
Description: Compliance filing Section 34 to be effective 4/1/2016.
Filed Date: 4/18/16.
Accession Number: 20160418–5202.
Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–856–000.
Applicants: Transcontinental Gas Pipe Line Company.
Description: Compliance filing Docket Nos. RP06–569–008 and RP07–376–005 (consolidated) Compliance Filing to be effective 7/20/2010.
Filed Date: 4/18/16.
Accession Number: 20160418–5225.
Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–857–000.
Applicants: Eastern Shore Natural Gas Company.
Description: Compliance filing Order on Compliance with Order to be effective 4/18/2016.
Filed Date: 4/18/16.
Accession Number: 20160418–5247.
Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–858–000.
Applicants: WestGas InterState, Inc.
Description: Compliance filing NAESB Compliance Filing to be effective 4/16/2016.
Filed Date: 4/18/16.
Accession Number: 20160418–5271.
Comments Due: 5 p.m. ET 5/2/16.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and § 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP16–422–001.
Applicants: Monroe Gas Storage Company, LLC.
Description: Compliance filing Monroe Gas Storage April 2016 Filing for Docket No. RP16–422–000 to be effective 4/1/2016.
Filed Date: 4/18/16.
Accession Number: 20160418–5230.
Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–423–001.
Applicants: Perryville Gas Storage LLC.
Description: Compliance filing Perryville Gas Storage April 2016 Filing Docket No. RP16–423–000 to be effective 4/1/2016.
Filed Date: 4/18/16.
Accession Number: 20160418–5223.
Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–424–001.
Applicants: Cadeville Gas Storage LLC.
Description: Compliance filing Cadeville Gas Storage April 2016 Filing Docket No. RP16–424–000 to be effective 4/1/2016.
Filed Date: 4/18/16.
Accession Number: 20160418–5227.
Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–452–001.
Applicants: Sierrita Gas Pipeline LLC.
Description: Compliance filing NAESB 3.0 Compliance Filing to be effective 4/1/2016.
Filed Date: 4/18/16.
Accession Number: 20160418–5173.
Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–457–001.
Applicants: Young Gas Storage Company, Ltd.
Description: Compliance filing NAESB 3.0 Compliance Filing to be effective 4/1/2016.
Filed Date: 4/18/16.
Accession Number: 20160418–5113.
Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–458–001.
Applicants: Mojave Pipeline Company, L.L.C.
Description: Compliance filing NAESB 3.0 Compliance Filing to be effective 4/1/2016.
Filed Date: 4/18/16.
Accession Number: 20160418–5165.
Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–460–001.
Applicants: Dominion Carolina Gas Transmission, LLC.
Description: Compliance filing NAESB Compliance Filing to be effective 4/1/2016.
Filed Date: 4/18/16.
Accession Number: 20160418–5002.
Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–473–001.
Applicants: High Island Offshore System, L.L.C.
Description: Compliance filing Order 587 Compliance Filing to be effective 4/1/2016.
Filed Date: 4/18/16.
Accession Number: 20160418–5139.
Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–480–001.
Applicants: Stingray Pipeline Company, L.L.C.
Description: Compliance filing Stingray Compliance Filing to be effective 4/1/2016.
Filed Date: 4/18/16.
Accession Number: 20160418–5089
Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–483–001.
Applicants: Panther Interstate Pipeline Energy, LLC.
Description: Compliance filing Panther Compliance Filing to be effective 4/1/2016.
Filed Date: 4/18/16.
Accession Number: 20160418–5086.
Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–492–001.
Applicants: USG Pipeline Company, LLC.
Description: Compliance filing Order No. 587–W Second Compliance Filing to be effective 4/1/2016.
Filed Date: 4/18/16.
Accession Number: 20160418–5129.
Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–498–001.
Applicants: MarkWest New Mexico, L.L.C.
Description: Compliance filing MarkWest New Mexico Compliance Filing to be effective 4/1/2016.
Filed Date: 4/18/16.
Accession Number: 20160418–5087.
Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–502–001.
Applicants: MarkWest Pioneer, L.L.C.
Description: Compliance filing MarkWest Pioneer Compliance Filing to be effective 4/1/2016.
Filed Date: 4/18/16.
Accession Number: 20160418–5088.
Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–506–001.
Applicants: KPC Pipeline, LLC.

Description: Compliance filing KPC Compliance Filing to be effective 4/1/2016.

Filed Date: 4/18/16.

Accession Number: 20160418–5081.

Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–507–001.

Applicants: NGO Transmission, Inc.

Description: Compliance filing NGO Transmission Compliance Filing to be effective 4/1/2016.

Filed Date: 4/18/16.

Accession Number: 20160418–5077.

Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–508–001.

Applicants: Ryckman Creek Resources, LLC.

Description: Compliance filing NAESB 3.0 Compliance Filing to be effective 4/1/16.

Filed Date: 4/18/16.

Accession Number: 20160418–5080.

Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–510–001.

Applicants: B–R Pipeline Company.

Description: Compliance filing Order No. 587–W Second Compliance Filing to be effective 4/1/2016.

Filed Date: 4/18/16.

Accession Number: 20160418–5130.

Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–512–001.

Applicants: WBI Energy Transmission, Inc.

Description: Compliance filing Compliance Filing with Order Issued March 29 on Order Nos. 587–W & 809 to be effective 4/1/16.

Filed Date: 4/18/16.

Accession Number: 20160418–5138.

Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–518–001.

Applicants: DBM Pipeline, LLC.

Description: Compliance filing DBM Pipeline Compliance Filing to be effective 4/1/16.

Filed Date: 4/18/16.

Accession Number: 20160418–5079.

Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–522–001.

Applicants: Black Hills Shoshone Pipeline, LLC.

Description: Compliance filing NAESB 3.0 Compliance Filing to be effective 4/1/16.

Filed Date: 4/18/16.

Accession Number: 20160418–5083.

Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–528–001.

Applicants: Columbia Gulf Transmission, LLC.

Description: Compliance filing Order 809 & NAESB 3.0 April Compliance Filing to be effective 4/1/16.

Filed Date: 4/18/16.

Accession Number: 20160418–5177

Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–529–001.

Applicants: Crossroads Pipeline Company.

Description: Compliance filing GEH—Order No. 809 & NAESB 3.0 April Compliance Filing to be effective 4/1/16.

Filed Date: 4/18/16.

Accession Number: 20160418–5178.

Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–531–001.

Applicants: Boardwalk Storage Company, LLC.

Description: Compliance filing Compliance Filing in Docket No. RP16–531–000 to be effective 4/1/16.

Filed Date: 4/18/16.

Accession Number: 20160418–5180.

Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–532–001.

Applicants: Hardy Storage Company, LLC.

Description: Compliance filing Order 809 & NAESB 3.0 April Compliance Filing to be effective 4/1/16.

Filed Date: 4/18/16.

Accession Number: 20160418–5179.

Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–545–002.

Applicants: Rendezvous Pipeline Company, LLC.

Description: Compliance filing NAESB 3.0 Compliance Filing to be effective 4/1/16.

Filed Date: 4/18/16.

Accession Number: 20160418–5071.

Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–548–001.

Applicants: Trans-Union Interstate Pipeline, L.P.

Description: Compliance filing Compliance Filing for March 29th Order to be effective 4/1/16.

Filed Date: 4/18/16.

Accession Number: 20160418–5157.

Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–549–001.

Applicants: PGPipeline LLC.

Description: Compliance filing NAESB 3.0 Compliance Filing to be effective 4/1/16.

Filed Date: 4/18/16.

Accession Number: 20160418–5070.

Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–551–001.

Applicants: Maritimes & Northeast Pipeline, L.L.C.

Description: Compliance filing Maritimes RP16–551 Compliance Filing to be effective 4/1/16.

Filed Date: 4/18/16.

Accession Number: 20160418–5124.

Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–552–001.

Applicants: Millennium Pipeline Company, LLC.

Description: Compliance filing GEH—Order No 809 & NAESB 3.0 April Compliance Filing to be effective 4/1/16.

Filed Date: 4/18/16.

Accession Number: 20160418–5183.

Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–553–001.

Applicants: Central Kentucky Transmission Company.

Description: Compliance filing GEH Order 809 & NAESB 3.0 April Compliance Filing to be effective 4/1/16.

Filed Date: 4/18/16.

Accession Number: 20160418–5181.

Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–554–001.

Applicants: Arlington Storage Company, LLC.

Description: Compliance filing Arlington Storage Company, LLC.—Order No. 587–W Directed Changes to be effective 4/1/16.

Filed Date: 4/18/16.

Accession Number: 20160418–5091.

Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–555–001.

Applicants: Tres Palacios Gas Storage LLC.

Description: Compliance filing Tres Palacios Gas Storage LLC.—Order No. 587–W Directed Changes to be effective 4/1/16.

Filed Date: 4/18/16.

Accession Number: 20160418–5099.

Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–558–001.

Applicants: Stagecoach Pipeline & Storage Company LL.

Description: Compliance filing Stagecoach Pipeline & Storage Company LLC.—Order No. 587–W Directed Changes to be effective 4/1/16.

Filed Date: 4/18/16.

Accession Number: 20160418–5098.

Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–566–001.

Applicants: Total Peaking Services, L. L. C.

Description: Compliance filing TPS Order No. 809 Compliance Filing Order Changes to be effective 4/1/16.

Filed Date: 4/18/16.

Accession Number: 20160418–5204.

Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–570–001.

Applicants: Cheniere Creole Trail Pipeline, L.P.

Description: Compliance filing NAESB 3.0 Compliance Filing to be effective 4/1/2016.

Filed Date: 4/18/16.

Accession Number: 20160418–5273.

Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–577–001.

Applicants: Northwest Pipeline LLC.

Description: Compliance filing NAESB 3.0 Compliance Filing (2) to be effective 4/1/2016.

Filed Date: 4/18/16.

Accession Number: 20160418–5272.

Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–584–001.

Applicants: WestGas InterState, Inc.

Description: Compliance filing 20160418_NAESB Compliance Filing to be effective 4/1/2016.

Filed Date: 4/18/16.

Accession Number: 20160418–5233.

Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–597–002.

Applicants: Tallgrass Interstate Gas Transmission, L.

Description: Compliance filing Order No. 587–W Compliance Filing to be effective 4/1/2016.

Filed Date: 4/18/16.

Accession Number: 20160418–5172.

Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–598–002.

Applicants: Rockies Express Pipeline LLC.

Description: Compliance filing Order No. 587–W Compliance Filing to be effective 4/1/2016.

Filed Date: 4/18/16.

Accession Number: 20160418–5171.

Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–599–002.

Applicants: Trailblazer Pipeline Company LLC.

Description: Compliance filing Order No. 587 W Compliance to be effective 4/1/2016.

Filed Date: 4/18/16.

Accession Number: 20160418–5174.

Comments Due: 5 p.m. ET 5/2/16.

Docket Numbers: RP16–800–001.

Applicants: Texas Gas Transmission, LLC.

Description: Tariff Amendment: Amendment to Filing (RP16–800) to be effective 4/1/2016.

Filed Date: 4/18/16.

Accession Number: 20160418–5115.

Comments Due: 5 p.m. ET 5/2/16.

Any person desiring to protest in any of the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 19, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–09823 Filed 4–26–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER16–1033–001.

Applicants: Windrose Power and Gas LLC.

Description: Tariff Amendment: Market Based Rate Tariff to be effective 5/5/2016.

Filed Date: 4/21/16.

Accession Number: 20160421–5055.

Comments Due: 5 p.m. ET 5/12/16.

Docket Numbers: ER16–1476–000.

Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: 2016 Revised Added Facilities Rate under TO—Filing No. 1 to be effective 1/1/2016.

Filed Date: 4/21/16.

Accession Number: 20160421–5001.

Comments Due: 5 p.m. ET 5/12/16.

Docket Numbers: ER16–1477–000.

Applicants: NSTAR Electric Company.

Description: Notice of Termination of NSTAR Electric Company of 1993 Interconnection Agreement Rate Schedule No. 176.

Filed Date: 4/20/16.

Accession Number: 20160420–5171.

Comments Due: 5 p.m. ET 5/11/16.

Docket Numbers: ER16–1479–000.

Applicants: Kentucky Utilities Company.

Description: § 205(d) Rate Filing: Brown Solar Depreciation Rates to be effective 12/31/9998.

Filed Date: 4/21/16.

Accession Number: 20160421–5027.

Comments Due: 5 p.m. ET 5/12/16.

Docket Numbers: ER16–1480–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2016–04–21_SA 6507 White Pine 1 SSR Renewal to be effective 4/16/2016.

Filed Date: 4/21/16.

Accession Number: 20160421–5038.

Comments Due: 5 p.m. ET 5/12/16.

Docket Numbers: ER16–1481–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2016–04–21_Schedule 43H Renewal White Pine 1 SSR to be effective 4/16/2016.

Filed Date: 4/21/16.

Accession Number: 20160421–5041.

Comments Due: 5 p.m. ET 5/12/16.

Take notice that the Commission received the following PURPA 210(m)(3) filings:

Docket Numbers: QM16–2–000.

Applicants: Ameren Illinois Company, Union Electric Company.

Description: Application of Ameren Illinois Company and Union Electric Company to Terminate Mandatory Purchase Obligation Under the Public Utility Regulatory Policies Act.

Filed Date: 4/20/16.

Accession Number: 20160420–5193.

Comments Due: 5 p.m. ET 5/18/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 21, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–09822 Filed 4–26–16; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OGC–2016–0237; FRL 9945–73–OGC]

Proposed Consent Decree, Clean Air Act Citizen Suit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed consent decree; request for public comment.

SUMMARY: In accordance with section 113(g) of the Clean Air Act, as amended ("CAA" or the "Act"), notice is hereby given of a proposed consent decree to address a lawsuit filed by Sierra Club and the Louisiana Environmental Action Network (collectively

"Plaintiffs") in the United States District Court for the Middle District of Louisiana: *Louisiana Environmental Action Network* v. *McCarthy,* Civil Action No. 3:15–cv–00858–JJB–RLB (M.D. L.A.). On December 23, 2015, Plaintiffs filed a complaint and amended complaint alleging that Gina McCarthy, in her official capacity as Administrator of the United States Environmental Protection Agency ("EPA"), failed to perform a non-discretionary duty to grant or deny within 60 days a petition submitted by Plaintiffs on May 19, 2015 requesting that EPA object to a CAA Title V permit issued by the Louisiana Department of Environmental Quality ("LDEQ"), to Yuhuang Chemical Inc., authorizing the construction and operation of the Yuhuang methanol manufacturing plant in St. James, Louisiana. The proposed consent decree would establish a deadline for EPA to take such action.

DATES: Written comments on the proposed consent decree must be received by May 27, 2016.

ADDRESSES: Submit your comments, identified by Docket ID number EPA–HQ–OGC–2016–0237, online at *http://www.regulations.gov* (EPA's preferred method); by email to *oei.docket@epa.gov;* by mail to EPA Docket Center, Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; or by hand delivery or courier to EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC, between 8:30 a.m. and 4:30 p.m. Monday through Friday, excluding legal holidays. Comments on a disk or CD–ROM should be formatted in Word or ASCII file, avoiding the use of special characters and any form of encryption, and may be mailed to the mailing address above.

FOR FURTHER INFORMATION CONTACT: John Krallman, Air and Radiation Law Office (2344A), Office of General Counsel, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone: (202) 564–0904; fax number (202) 564–5603; email address: *krallman.john@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Additional Information About the Proposed Consent Decree

The proposed consent decree would resolve a lawsuit filed by the Plaintiffs seeking to compel the Administrator to take actions under CAA section 505(b)(2). Under the terms of the proposed consent decree, EPA would agree to sign its response granting or denying the petition filed by Plaintiffs regarding the Yuhuang methanol manufacturing plant located in St. James, Louisiana, pursuant to section 505(b)(2) of the CAA, on or before September 1, 2016.

Under the terms of the proposed consent decree, EPA would expeditiously deliver notice of EPA's response to the Office of the Federal Register for review and publication following signature of such response. In addition, the proposed consent decree outlines the procedure for the Plaintiffs to request costs of litigation, including attorney fees.

For a period of thirty (30) days following the date of publication of this notice, the Agency will accept written comments relating to the proposed consent decree from persons who are not named as parties or intervenors to the litigation in question. EPA or the Department of Justice may withdraw or withhold consent to the proposed consent decree if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act. Unless EPA or the Department of Justice determines that consent to this consent decree should be withdrawn, the terms of the consent decree will be affirmed.

II. Additional Information About Commenting on the Proposed Consent Decree

A. How can I get a copy of the consent decree?

The official public docket for this action (identified by Docket ID No EPA–HQ–OGC–2016–0237) contains a copy of the proposed consent decree. The official public docket is available for public viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OEI Docket is (202) 566–1752.

An electronic version of the public docket is available through *http://www.regulations.gov.* You may use *http://www.regulations.gov* to submit or view public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Once in the system, key in the appropriate docket identification number then select "search."

It is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing online at *http://www.regulations.gov* without change, unless the comment contains copyrighted material, confidential business information (CBI), or other information whose disclosure is restricted by statute. Information claimed as CBI and other information whose disclosure is restricted by statute is not included in the official public docket or in the electronic public docket. EPA's policy is that copyrighted material, including copyrighted material contained in a public comment, will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the EPA Docket Center.

B. How and to whom do I submit comments?

You may submit comments as provided in the **ADDRESSES** section. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an email address or other contact information in the body of your comment and with any disk or CD–ROM you submit. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Use of the *http://www.regulations.gov* Web site to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an "anonymous access" system, which means EPA will not know your identity, email address, or other contact information unless you provide it in the body of your comment.

In contrast to EPA's electronic public docket, EPA's electronic mail (email) system is not an "anonymous access" system. If you send an email comment directly to the Docket without going through *www.regulations.gov,* your email address is automatically captured and included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

Dated: April 19, 2016.

Lorie J. Schmidt,

Associate General Counsel.

[FR Doc. 2016–09859 Filed 4–26–16; 8:45 am]

BILLING CODE P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2012–0691; FRL–9945–32–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; NESHAP for Mercury Cell Chlor-Alkali Plants (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), "NESHAP for Mercury Cell Chlor-Alkali Plants (40 CFR part 63, subpart IIIII) (Renewal)" (EPA ICR No. 2046.08, OMB Control No. 2060–0542), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This is a proposed extension of the ICR, which is currently approved through April 30, 2016. Public comments were previously requested via the **Federal Register** (80 FR 32116) on June 5, 2015 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An Agency may neither conduct nor sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before May 27, 2016.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OECA–2012–0691, to: (1) EPA online using *www.regulations.gov* (our preferred method), or by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460; and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI), or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Patrick Yellin, Monitoring, Assistance, and Media Programs Division, Office of Compliance, Mail Code 2227A, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–2970; email address: *yellin.patrick@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit: *http://www.epa.gov/dockets.*

Abstract: Owners and operators of affected facilities are required to comply with reporting and record keeping requirements for the general provisions of 40 CFR part 63, subpart A, as well as for the specific requirements at 40 CFR part 63, subpart IIIII. This includes submitting initial notification reports, performance tests and periodic reports and results, and maintaining records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These reports are used by EPA to determine compliance with these standards.

Form Numbers: None.

Respondents/affected entities: Mercury cell chlor-alkali plants.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart IIIII).

Estimated number of respondents: 2 (total).

Frequency of response: Initially and semiannually.

Total estimated burden: 3,760 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $394,000 (per year), which includes in $16,400 annualized capital/startup and/or operation & maintenance costs.

Changes in the estimates: There is a small adjustment increase in the respondent labor hours as currently identified in the OMB Inventory of Approved Burdens. The increase is due to a change in assumption. In this ICR, we assume all existing sources will take some time each year to re-familiarize themselves with the regulatory requirements.

Courtney Kerwin,

Acting-Director, Collection Strategies Division.

[FR Doc. 2016–09891 Filed 4–26–16; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meeting

Notice of a Matter To Be Added to the Agenda for Consideration at an Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that the following matter will be added to the "Discussion Agenda" for consideration at the open meeting of the Board of Directors of the Federal Deposit Insurance Corporation scheduled to be held at 10:00 a.m. on Tuesday, April 26, 2016, in the Board Room on the sixth floor of the FDIC Building located at 550–17th Street NW., Washington, DC:

Memorandum and resolution re: Notice of Proposed Rulemaking to Implement Liquidity Risk Standards for Certain FDIC Supervised Institutions.

Requests for further information concerning the meeting may be directed to Mr. Robert E. Feldman, Executive Secretary of the Corporation, at 202–898–7043.

Dated: April 22, 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–09924 Filed 4–25–16; 11:15 am]

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FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that the Federal Deposit Insurance

Corporation's Board of Directors will meet in open session at 10:00 a.m. on Tuesday, April 26, 2016, to consider the following matters:

Summary Agenda: No substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

Disposition of minutes of previous Board of Directors' Meetings.

Memorandum and resolution re: Notice of Final Rulemaking: Revisions to Part 341 of the FDIC's Rules and Regulations Requiring the Registration of Securities Transfer Agents.

Summary reports, status reports, and reports of actions taken pursuant to authority delegated by the Board of Directors.

Discussion Agenda

Memorandum and resolution re: Notice of Proposed Rulemaking: Incentive-based Compensation Arrangements.

Memorandum and resolution re: Deposit Insurance Assessments for Small Banks.

The meeting will be held in the Board Room located on the sixth floor of the FDIC Building located at 550 17th Street NW., Washington, DC.

This Board meeting will be Webcast live via the Internet and subsequently made available on-demand approximately one week after the event. Visit *https://fdic.primetime.mediaplatform.com/#!/channel/1232003497484/Board+Meetings* to view the event. If you need any technical assistance, please visit our Video Help page at: *https://www.fdic.gov/video.html.*

The FDIC will provide attendees with auxiliary aids (*e.g.*, sign language interpretation) required for this meeting. Those attendees needing such assistance should call 703–562–2404 (Voice) or 703–649–4354 (Video Phone) to make necessary arrangements.

Requests for further information concerning the meeting may be directed to Mr. Robert E. Feldman, Executive Secretary of the Corporation, at 202–898–7043.

Dated: April 20, 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–09923 Filed 4–25–16; 11:15 am]

BILLING CODE P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (*www.fmc.gov*) or by contacting the Office of Agreements at (202) 523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 011961–021.

Title: The Maritime Credit Agreement.

Parties: Maersk Line A/S; Cosco Container Lines Company Limited; Hanjin Shipping Co., Ltd.; Kawasaki Kisen Kaisha Ltd.; United Arab Shipping Company; Wallenius Wilhelmsen Logistics AS; and Zim Integrated Shipping Services, Ltd.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Conner; 1200 19th Street NW., Washington, DC 20036.

Synopsis: The amendment deletes China Shipping Container Lines Co. Ltd. as a party to the Agreement.

Agreement No.: 012067–015.

Title: U.S. Supplemental Agreement to HLC Agreement.

Parties: BBC Chartering Carriers GmbH & Co. KG and BBC Chartering & Logistic GmbH & Co. KG, as a single member; Chipolbrok (Chinese-Polish Joint Stock Shipping Company); Hanssy Shipping Pte. Ltd.; Hyundai Merchant Marine Co., Ltd.; Industrial Maritime Carriers, L.L.C.; Nordana Line A/S; and Rickmers-Linie GmbH & Cie. KG.

Filing Party: Wade S. Hooker, Esq.; 211 Central Park W; New York, NY 10024.

Synopsis: The amendment deletes Safmarine MPV N.V. as a party to the U.S. Agreement and the worldwide HLC Agreement.

Agreement No.: 012327–003.

Title: "K" Line/WHL/WHS/PIL Space Charter and Sailing Agreement.

Parties: Kawasaki Kisen Kaisha, Ltd.; Wan Hai Lines (Singapore) PTE Ltd.; Wan Hai Lines Ltd.; Pacific International Lines (PTE) Ltd.

Filing Party: Eric. C. Jeffrey, Esq.; Nixon Peabody LLP; 799 9th Street NW., Suite 500; Washington, DC 20001.

Synopsis: The amendment adds Vietnam to the geographic scope of the Agreement.

Agreement No.: 012400.

Title: Trailer Bridge/Marinex Cargo Line Space Charter Agreement.

Parties: Trailer Bridge, Inc. and Marinex Cargo Line.

Filing Party: Keith B. Letourneau, Esq.; Blank Rome, LLP; 717 Texas Avenue; Suite 1400; Houston, TX 77002.

Synopsis: The agreement authorizes Marinex to charter space to Trailer Bridge in the trade between Puerto Rico on the one hand, and St. Maarten, St. Croix, St. Thomas, and Tortola on the other hand.

Agreement No.: 012401.

Title: Trailer Bridge/America Cruise Ferries Space Charter Agreement.

Parties: Trailer Bridge, Inc. and American Cruise Ferries, Inc.

Filing Party: Keith B. Letourneau, Esq.; Blank Rome, LLP; 717 Texas Avenue; Suite 1400; Houston, TX 77002.

Synopsis: The agreement authorizes American Cruise Ferries to charter space to Trailer Bridge in the trade between Puerto Rico and the Dominican Republic.

Agreement No.: 012402.

Title: APL/Hamburg Sud Space Charter Agreement.

Parties: Hamburg Sud; and APL Co. Pte Ltd. and American President Lines, Ltd. (collectively "APL").

Filing Party: Eric. C. Jeffrey, Esq.; Nixon Peabody LLP; 799 9th Street NW., Suite 500; Washington, DC 20001.

Synopsis: The agreement authorizes APL to charter space to Hamburg Sud in the trade from China, Hong Kong, and Korea to the United States Pacific Northwest.

Agreement No.: 012403.

Title: MOL/ZIM Slot Exchange Agreement.

Parties: Mitsui O.S.K. Lines, Ltd. and Zim Integrated Shipping Services Co., Ltd.

Filing Party: Mark E. Newcomb; ZIM American Integrated Shipping Services, Co. LLC; 5801 Lake Wright Dr.; Norfolk, VA 23508.

Synopsis: The agreement authorizes the parties to exchange slots on each other's services in the trade between the U.S. on the one hand; and China, Korea, Malaysia, Panama, Saudi Arabia, Singapore, Sri Lanka, Taiwan, and Vietnam on the other hand.

Agreement No.: 012404.

Title: COSCON/UASC Slot Charter Agreement Asia—USWC.

Parties: COSCO Container Lines Co. Ltd. and United Arab Shipping Co., S.A.G.

Filing Party: Eric. C. Jeffrey, Esq.; Nixon Peabody LLP; 799 9th Street NW., Suite 500; Washington, DC 20001.

Synopsis: The agreement provides for the exchange of slots between COSCON and UASC on their respective services in the trade between the United States West Coast and China (including Hong Kong), Korea, Malaysia, Singapore, and Vietnam.

Agreement No.: 201232–001.

Title: NYSA–ILA Assessment Agreement.

Parties: International Longshoremen's Association and New York Shipping Association.

Filing Parties: Donato Caruso, Esq.; The Lambos Firm, LLP; 303 South Broadway,Suite 410; Tarrytown, NY 10591 and Andre Mazzola, Esq.; Marrinan & Mazzola Mardon, P.C.; 26 Broadway, 17th Floor; New York, NY 10004.

Synopsis: The amendment reduces the assessment for all House Containers Within 260 Miles to $89.00 per container in all trades except in the Bermuda Trade.

By Order of the Federal Maritime Commission.

Dated: April 22, 2016.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2016–09845 Filed 4–26–16; 8:45 am]

BILLING CODE 6731–AA–P

FEDERAL MARITIME COMMISSION

Agency Information Collection Activities: 60-Day Public Comment Request

AGENCY: Federal Maritime Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of our continuing effort to reduce paperwork and respondent burden, and as required by the Paperwork Reduction Act of 1995, the Federal Maritime Commission (Commission) invites comments on the continuing information collection (extension with no changes) listed below in this notice.

DATES: Written comments must be submitted on or before June 27, 2016.

ADDRESSES: Address all comments to: Vern W. Hill, Managing Director, Office of the Managing Director, Federal Maritime Commission, 800 North Capitol Street NW., Washington, DC 20573, Phone: (202) 523–5800, Email: *omd@fmc.gov.*

Please send separate comments for each specific information collection listed below. You must reference the information collection's title and OMB number in your comments.

FOR FURTHER INFORMATION CONTACT: Copies of the information collections and instructions, or copies of any comments received, may be obtained by contacting Donna Lee on (202) 523–5800 or email at *dlee@fmc.gov.*

SUPPLEMENTARY INFORMATION:

Request for Comments

The Commission, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on the continuing information collection listed in this notice, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Comments submitted in response to this notice will be included or summarized in our request for Office of Management and Budget (OMB) approval of the relevant information collection. All comments are part of the public record and subject to disclosure. Please do not include any confidential or inappropriate material in your comments. We invite comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Information Collection Open for Comment

Title: 46 CFR part 532—NVOCC Negotiated Rate Arrangements.

OMB Approval Number: 3072–0071 (Expires July 31, 2016).

Abstract: Section 16 of the Shipping Act of 1984, 46 U.S.C. 40103, authorizes the Commission to exempt by order or regulation "any class of agreements between persons subject to this [Act] or any specified activity of those persons from any requirement of this [Act] if the Commission finds that the exemption will not result in substantial reduction in competition or be detrimental to commerce." The Commission may attach conditions to any exemption and may, by order, revoke an exemption. In 46 CFR part 532, the Commission exempted non-vessel-operating common carriers (NVOCCs) from the tariff rate publication requirements of Part 520, and allowed an NVOCC to enter into an NVOCC Negotiated Rate Arrangement (NRA) in lieu of publishing its tariff rate(s), provided the NVOCC posts a prominent notice in its rules tariff invoking the NRA exemption and provides electronic access to its rules tariff to the public free of charge. This information collection corresponds to the rules tariff prominent notice and the requirement to make its tariff publicly available free of charge.

Current Actions: There are no changes to this information collection, and it is being submitted for extension purposes only.

Type of Review: Extension.

Needs and Uses: The Commission uses the information filed by an NVOCC in its rules tariff to determine whether the NVOCC has invoked the exemption for a particular shipment or shipments. The Commission has used and will continue to use the information required to be maintained by NVOCCs for monitoring and investigatory purposes, and, in its proceedings, to adjudicate related issues raised by private parties.

Frequency: An NVOCC invokes the NRA exemption by publishing a prominent notice in its rules tariff once.

Type of Respondents: NVOCCs.

Number of Annual Respondents: 255. While there has been a substantial decrease in the number of annual responses, in 2013 the NRA exemption was extended to include foreign unlicensed NVOCCs, which resulted in a "one-time" increase in the number of annual respondents to 626. The Commission expects the number of annual respondents to remain at 255 in the future, as new NVOCCs enter the market and some invoke the exemption.

Estimated Time per Response: 15 minutes for those adding a tariff rule to use a combination of tariff rates and NRAs. One hour for those who make their tariff rules publicly available by opting to use NRAs exclusively and posting them to their Web site.

Total Annual Burden: Based on the number of NVOCCs who have filed a rule or prominent notice in their respective tariffs, we calculate that 25% of new NVOCCs will use the NRA exemption. Of those, about 3% will use NRAs exclusively. Almost all will likely use similar language invoking the exemption in their tariffs. For the 255 annual respondents, the total burden is calculated as follows:

8 × 1 hour = 8 hours (3% using NRAs exclusively)

247 × .25 hour = 61.75 hours rounded to 62 (combination of tariff rates and NRAs)

Total annual burden is estimated to be 70 hours.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2016–09817 Filed 4–26–16; 8:45 am]

BILLING CODE 6731–AA–P

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

[BAC 6735–01]

Sunshine Act Notice

April 25, 2016.

TIME AND DATE: 10:00 a.m., Thursday, May 5, 2016.

PLACE: The Richard V. Backley Hearing Room, Room 511N, 1331 Pennsylvania Avenue NW., Washington, DC 20004 (enter from F Street entrance).

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following in open session: *Secretary of Labor on behalf of Charles Riordan* v. *Knox Creek Coal Corporation*, Docket No. VA 2014–343–D (Issues include whether, in this discrimination case, substantial evidence supports the Judge's determination that the miner engaged in protected activity and that the proffered reason for his employment termination was pretextual.)

Any person attending this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR 2706.150(a)(3) and 2706.160(d).

CONTACT PERSON FOR MORE INFO: Emogene Johnson (202) 434–9935/(202) 708–9300 for TDD Relay/1–800–877–8339 for toll free.

Sarah L. Stewart,

Deputy General Counsel.

[FR Doc. 2016–09967 Filed 4–25–16; 4:15 pm]

BILLING CODE 6735–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

OMB Control No. 9000–0058; Docket 2016–0053; Sequence 9]

Submission for OMB Review; Schedules for Construction Contracts

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comment regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning schedules for construction contracts. A notice was published in the **Federal Register** at 81 FR 7799 on February 16, 2016. No comments were received.

DATES: Submit comments on or before May 27, 2016.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for GSA, Room 10236, NEOB, Washington, DC 20503. Additionally submit a copy to GSA by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link "Submit a Comment" that corresponds with "Information Collection 9000–0058, Schedules for Construction Contracts". Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "Information Collection 9000–0058, Schedules for Construction Contracts" on your attached document.

- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 9000–0058, Schedules for Construction Contracts.

Instructions: Please submit comments only and cite Information Collection 9000–0058, Schedules for Construction Contracts, in all correspondence related to this collection. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Curtis E. Glover, Sr., Procurement Analyst, Office of Acquisition Policy, 202–501–1448 or email *curtis.glover@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

Federal construction contractors may be required to submit schedules, in the form of a progress chart, showing the order in which the Contractor proposes to perform the work. In accordance with FAR 52.236–15, Schedules for Construction Contracts, the Contractor shall, within five days after work commences on the contract or another period of time determined by the contracting officer, prepare and submit to the contracting officer for approval three copies of a practicable schedule showing the order in which the Contractor proposes to perform the work, and the dates on which the Contractor contemplates starting and completing the several salient features of the work (including acquiring materials, plants, and equipment). This information is used to monitor progress under a Federal construction contract when other management approaches for ensuring adequate progress are not used. If the Contractor fails to submit a schedule within the time prescribes, the Contracting Officer may withhold approval of progress payments until the Contractor submits the required schedule.

B. Annual Reporting Burden

Respondents: 3,804.

Responses per Respondent: 2.

Annual Responses: 7,608.

Hours per Response: 4.

Total Burden Hours: 30,432.

Affected Public: Businesses or other for-profit and not-for-profit institutions.

Frequency: On occasion.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0058, Schedules for Construction Contracts, in all correspondence.

Dated: April 21, 2016.

Lorin S. Curit,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2016–09742 Filed 4–26–16; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0029; Docket 2016–0053; Sequence 10]

Submission for OMB Review; Extraordinary Contractual Action Requests

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration NASA).

ACTION: Notice of request for comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning extraordinary contractual action requests. A notice was published in the **Federal Register** at 81 FR 7798 on February 16, 2016. No comments were received.

DATES: Submit comments on or before May 27, 2016.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for GSA, Room 10236, NEOB, Washington, DC 20503. Additionally submit a copy to GSA by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link "Submit a Comment" that corresponds with "Information Collection 9000–0029, Extraordinary Contractual Action Requests". Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "Information Collection 9000–0029, Extraordinary Contractual Action Requests" on your attached document.
- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 9000–0029, Extraordinary Contractual Action Requests.

Instructions: Please submit comments only and cite Information Collection 9000–0029, Extraordinary Contractual Action Requests, in all correspondence related to this collection. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Cecelia L. Davis, Procurement Analyst, Office of Governmentwide Acquisition Policy, GSA, at 202–219–0202 or email at *cecelia.davis@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

FAR subpart 50.1 prescribes policies and procedures that allow contracts to be entered into, amended, or modified in order to facilitate national defense under the extraordinary emergency authority granted under 50 U.S.C. 1431 *et seq.* and Executive Order (E.O.) 10789 dated November 14, 1958, *et seq.*

This authority applies to the Government Printing Office; the Department of Homeland Security; the Tennessee Valley Authority; the National Aeronautics and Space Administration; the Department of Defense; the Department of the Army; the Department of the Navy; the Department of the Air Force; the Department of the Treasury; the Department of the Interior; the Department of Agriculture; the Department of Commerce; and the Department of Transportation. Also included is the Department of Energy for functions transferred to that Department from other authorized agencies and any other agency that may be authorized by the President.

In order for a contractor to be granted relief under the FAR, specific evidence must be submitted which supports the firm's assertion that relief is appropriate and that the matter cannot be disposed of under the terms of the contract.

FAR 50.103–3 specifies the minimum information that a contractor must include in a request for contract adjustment in accordance with FAR 50–103–1 and 50.103–2.

FAR 50–103–4 sets forth additional information that the contracting officer or other agency official may request from the contractor to support any request made under FAR 50.103–3.

FAR 50.104–3 sets forth the information that the contractor shall include in a request for the indemnification clause to cover unusually hazardous or nuclear risks.

FAR 52.250–1, Indemnification under Public Law 850804, requires in paragraph (g) that the contractor shall promptly notify the contracting officer of any claim or action against, or loss by, the contractor or any subcontractors that may reasonably to involve indemnification under the clause.

The information is used by the Government to determine if relief can be granted under FAR and to determine the appropriate type and amount of relief.

B. Annual Reporting Burden

Respondents: 28.

Responses per Respondent: About 6.

Total Responses: 164.

Hours per Response: About 41.5.

Total Burden Hours: 6,800.

Obtaining Copies of Proposals: Requester may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0029, Extraordinary Contractual Action Requests, in all correspondence.

Dated: April 21, 2016.

Lorin S. Curit,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2016–09710 Filed 4–26–16; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[CDC–2014–0014; Docket Number NIOSH–275]

Issuance of Final Guidance Publication

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of issuance of final guidance publication.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), announces the availability of the following publication: *National Occupational Research Agenda (NORA) National Total Worker Health® Agenda (2016–2026): A National Agenda to Advance Total Worker Health® Research, Practice, Policy, and Capacity* [2016–114].

ADDRESSES: This document may be obtained at the following link *http://www.cdc.gov/niosh/docs/2016-114/.*

FOR FURTHER INFORMATION CONTACT: Sara L. Tamers, Ph.D., MPH, NIOSH/CDC, Telephone: (202) 245–0677, Fax: (202) 245–0664 (not toll-free numbers), email: *STamers@cdc.gov.*

Dated: April 22, 2016.

Frank J. Hearl,

Chief of Staff, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2016–09786 Filed 4–26–16; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: Child Support Noncustodial Parent Employment Demonstration (CSPED).

OMB No.: 0970–439.

Description: The Office of Child Support Enforcement (OCSE) within the Administration for Children and Families (ACF) seeks an extension without change for an existing data collection called the Child Support Noncustodial Parent Employment Demonstration (CSPED) through September 30, 2018 (OMB no. 0970–439; expiration date September 30, 2016). OCSE is proposing that this information collection be extended to continue using 8 of the 10 currently approved information collection instruments with a reduction in burden hours to reflect only the extension period, estimated to be two years and three months, from July 1, 2016 to September 30, 2018.

In October 2012, OCSE issued grants to eight state child support agencies to provide employment, parenting, and child support services to noncustodial parents who are having difficulty meeting their child support obligation. The overall objective of the CSPED evaluation is to document and evaluate the effectiveness of the approaches taken by these eight CSPED grantees. This evaluation will yield information about effective strategies for improving child support payments by providing noncustodial parents employment and other services through child support programs. It will generate extensive information on how these programs operated, what they cost, the effects the programs had, and whether the benefits of the programs exceed their costs. The information gathered will be critical to informing decisions related to future investments in child support-led employment-focused programs for noncustodial parents who have difficulty meeting their child support obligations.

The CSPED evaluation includes the following two interconnected components or "studies":

1. Implementation and Cost Study. The goal of the implementation and cost study is to provide a detailed description of the programs—how they are implemented, their participants, the contexts in which they are operated, their promising practices, and their costs. The detailed descriptions will assist in interpreting program impacts, identifying program features and conditions necessary for effective program replication or improvement, and carefully documenting the costs of delivering these services. Key activities of the implementation and cost study include: (1) Conducting semi-structured interviews with program staff and selected community partner organizations to gather information on program implementation and costs; (2) conducting focus groups with program participants to elicit participation experiences; (3) administering a web-based survey to program staff and community partners to capture broader staff program experiences; and (4) collecting data on study participant service use, dosage, and duration of enrollment throughout the demonstration using a web-based Management Information System (MIS).

2. Impact Study. The goal of the impact study is to provide rigorous estimates of the effectiveness of the eight programs using an experimental research design. Program applicants who are eligible for CSPED services are randomly assigned to either a program group that is offered program services or a control group that is not. The study MIS that documents service use for the implementation study is also used by grantee staff to conduct random assignment for the impact study. The impact study relies on data from surveys of participants, as well as administrative records from state and county data systems. Survey data are collected twice from program applicants. Baseline information is collected from all noncustodial parents who apply for the program prior to random assignment. A follow-up survey is collected from sample members twelve months after random assignment. A wide range of measures are collected through surveys, including measures of employment stability and quality, barriers to employment, parenting and co-parenting, and demographic and socio-economic characteristics. In addition, data on child support obligations and payments, Temporary Assistance for Needy Families (TANF) and Supplemental Nutrition Assistance Program (SNAP) benefits, Medicaid receipt, involvement with the criminal justice system, and earnings and benefit data collected through the Unemployment Insurance (UI) system are obtained from state and county databases.

Two components of the data collection have been completed: (1) Focus groups with program participants; and (2) the web-based survey to document program staff and partner experiences. The following data collection activities are not yet complete: (1) The staff interview topic guide; (2) the study MIS functions for tracking participation in the program; (3) the introductory script which program staff use to introduce the study to participants; (4) the introductory script heard by program applicants; (5) the baseline survey; (6) the study MIS functions for conducting random assignment; (7) the protocol for collecting child support, benefit, earnings, and criminal justice data from state and county administrative data systems; and (8) the 12-month follow-up survey. As of January 1, 2016, 8,060 participants have been enrolled and completed the baseline survey and over 2,300 participants have completed the 12-month follow-up survey.

Respondents

Respondents to these activities include program applicants, study participants, grantee staff and community partners, as well as state and county staff responsible for extracting data from government databases for the evaluation. Specific respondents per instrument are noted in the burden tables below.

Annual Burden Estimates

The following instruments are proposed for public comment under this 60-Day **Federal Register** Notice. The following table provides the burden estimates for the implementation and cost study and the impact study components of the current request. The requested extension period is estimated to be two years and three months, from July 1, 2016 to September 30, 2018. Thus, burden hours for all components are annualized over two years and three months.

IMPLEMENTATION AND COST STUDY

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours	Total annual burden hours[a]
Staff interview topic guide	120	1	1	120	53
Study MIS to track program participation	200	468.75	0.0333	3,125	1,390
Impact Study					
Introductory script:					
Grantee staff	120	9	0.1667	180	80
Program applicants[b]	1,050	1	0.1667	175	78
Baseline survey	1,000	1	0.5833	583	259
Study MIS to conduct random assignment	120	9	0.1667	180	80
Protocol for collecting administrative records	32	1	8	256	114
12 month follow-up survey	1,476	1	0.75	1,107	492

[a] All burden estimates are annualized over 2.25 years.

[b] Five percent of program applicants are not expected to agree to participate in the study; thus there are 5% more program applicants than study participants.

Estimated Total Annual Burden Hours: 2,546.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201. Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2016–09803 Filed 4–26–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–N–2016–1134]

Public Meeting on Patient-Focused Drug Development for Patients Who Have Received an Organ Transplant

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a public meeting and an opportunity for public comment on Patient-Focused Drug Development for patients who have received an organ transplant. Patient-Focused Drug Development is part of FDA's performance commitments made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to allow FDA to obtain patient perspectives on the impact of receiving an organ transplant on daily life and patient views on treatment approaches; the input from this public meeting will help in developing topics for further discussion. FDA is also interested in discussing issues related to scientific challenges in developing drugs to manage organ transplantation. In the afternoon, FDA will hold a workshop and provide information for and gain perspective from patients and patient advocacy organizations, health care providers, academic experts, and industry on various aspects of clinical development of drug products intended to manage organ transplantation.

DATES: The public meeting will be held on September 27, 2016, from 9 a.m. to 5 p.m. Please register here for the meeting by September 20, 2016: *http://organtransplantpfdd.eventbrite.com.* Submit electronic or written comments to the public docket by November 27, 2016.

ADDRESSES: The meeting and workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm.1503), Silver Spring, MD 20993–0002. Participants must enter through Building 1 and undergo security screening. For more information on parking and security procedures, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):*Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2016–N–1134 for "Public Meeting on Patient-Focused Drug Development for Patients Who Have Received an Organ Transplant." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION". The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FDA will post the agenda approximately 5 days before the meeting at: *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm495933.htm.*

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993, 301–796–5003, FAX: 301–847–8443, *graham.thompson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on Patient-Focused Drug Development

FDA has selected patients who have received an organ transplant as the focus of a public meeting under Patient-Focused Drug Development, an initiative that involves obtaining a better understanding of patient perspectives on the severity of a disease and the available therapies for these conditions. Patient-Focused Drug Development is being conducted to fulfill FDA performance commitments that are part of the reauthorization of the PDUFA under Title I of the Food and Drug Safety and Innovation Act (Pub. L. 112–144). The full set of performance commitments is available at *http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf.*

FDA committed to obtain the patient perspective on 20 disease areas during the course of PDUFA V. For each disease area, the Agency will conduct a public meeting to discuss the disease and its impact on patients' daily lives, the types of treatment benefit that matter most to patients, and patients' perspectives on the adequacy of the available therapies. These meetings will include participation of FDA review divisions, the relevant patient communities, and other interested stakeholders.

On July 2, 2015, FDA published a notice (80 FR 32816) in the **Federal Register** announcing the disease areas for meetings in fiscal years 2016–2017, final 2 years of PDUFA V time frame. The Agency used several criteria outlined in that notice to develop the list of disease areas. FDA obtained public comment on the Agency's proposed criteria and potential disease areas through a public docket. In selecting the set of disease areas, FDA carefully considered the public comments received and the perspectives of review divisions at FDA. More information, including the list of disease areas and a general schedule of meetings, is posted at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm.*

II. Public Meeting and Workshop Information

A. Purpose and Scope of the Meeting

The purpose of this Patient-Focused Drug Development meeting is to obtain input on organ transplantation and current approaches to management of organ transplantation. In 2015, over 25,000 people in the United States received an organ transplant. Organ transplantation requires pharmacologic and non-pharmacologic management before and after receipt. There are FDA-approved therapies used to assist the immune system in responding properly to the transplanted organ. Treatment requires a combination of drugs given for the lifetime of a transplanted organ. FDA is committed to working with all stakeholders to develop safe and effective therapies for affected individuals.

The questions that will be asked of patients and patient stakeholders at the meeting are listed in this section, organized by topic. For each topic, a brief initial patient panel discussion will begin the dialogue. This will be followed by a facilitated discussion inviting comments from other patient and patient stakeholder participants. In addition to input generated through this public meeting, FDA is interested in receiving patient input addressing these questions through written comments, which can be submitted to the public docket (see **ADDRESSES**). When submitting comments, if you are commenting on behalf of a child, please indicate that you are doing so and answer the following questions as much as possible from the patient's perspective.

Topic 1: Disease Symptoms and Daily Impacts That Matter Most to Patients

1. What have been the most significant changes in your overall health since you received your transplanted organ?

(a) How long has it been since you received your transplant?

2. Focusing on symptoms related to your organ transplant and post-transplant effects, which 1–3 symptoms have the most significant impact on your life? (Examples may include pain, infection, anxiety, etc.)

3. Are there specific activities that are important to you but that you cannot do at all or as fully as you would like because of your transplant? (Examples of activities may include sleeping through the night, driving, walking/running, exercising, etc.)

(a) How do your symptoms and their negative impacts affect your daily life on the best days? On the worst days? (Examples may include limitations on the ability to undertake physically strenuous activities, restrictions on the ability to travel, lack of appetite, fatigue, etc.)

4. How has your experience with your transplanted organ changed over time? Do particular symptoms come and go as your duration of time with a transplanted organ has increased? If so, do you know of anything that makes your symptoms better? Worse?

5. What worries you most about your health post-transplant?

Topic 2: Patients' Perspectives on Transplant and Treatment Impacts

1. What are you currently doing to maintain your transplanted organ or treat related health concerns following transplantation? (Examples may include immunosuppressants, antibiotics, antivirals, over-the-counter products, and other therapies including non-drug therapies)

(a) How has your post-transplant treatment regimen changed over time, and why?

2. How well does your current treatment regimen manage the most significant symptoms you experience post-transplantation?

(a) How well do these treatments improve your ability to do specific activities that are important to you in your daily life?

(b) How well have these treatments worked for you as your experiences post-transplant have changed over time?

3. What are the most significant downsides to your current treatments, and how do they affect your daily life? (Examples of downsides may include bothersome side effects, need for multiple medications, risk of infection, need for hospitalization, etc.)

(a) What are the biggest challenges you face in maintaining your post-transplant treatment regimen? (Examples of challenges may be bothersome side effects, need for multiple medications, etc.)

4. What specific things would you look for in an ideal treatment for managing your transplanted organ?

In the afternoon, discussion will be related to scientific topics, with the goal of understanding issues that may affect the development of drugs for the treatment of organ transplantation and identifying topics for future discussion. Discussion topics for the afternoon will include the following: Current treatment considerations, adherence, clinical trial designs, and clinical trial endpoints.

B. Meeting Attendance and Participation

If you wish to attend this meeting, visit *http://organtransplantpfdd.eventbrite.com.* Please register by September 20, 2016. If you are unable to attend the meeting in person, you can register to view a live Webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Webcast. Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of a disability, please contact Graham Thompson (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

Patients who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. These patients also must send to *PatientFocused@fda.hhs.gov* a brief summary of responses to the topic questions by September 12, 2016. Panelists will be notified of their selection approximately 7 days before the public meeting. We will try to accommodate all patients and patient stakeholders who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

FDA will hold an open public comment period to give the public an opportunity to comment. Registration for open public comment will occur at the registration desk on the day of the meeting and workshop on a first-come, first-served basis.

Docket Comments: Regardless of if you attend the public meeting, you can submit electronic or written responses to the questions pertaining to Topics 1 and 2 to the public docket (see **ADDRESSES**) by November 27, 2016. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Transcripts: As soon as a transcript is available, FDA will post it at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm495933.htm.*

Dated: April 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–09785 Filed 4–26–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0514]

Agency Information Collection Activities; Proposed Collection; Comment Request; Requests for Clinical Laboratory Improvement Amendments Categorization

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requests for Clinical Laboratory Improvement Amendments of 1998 (CLIA) categorization of in vitro diagnostic tests when a premarket review is not needed.

DATES: Submit either electronic or written comments on the collection of information by June 27, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2013–N–0514 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Requests for Clinical Laboratory Improvement Amendments Categorization." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Requests for Clinical Laboratory Improvement Amendments of 1988 Categorization—42 CFR 493.17—OMB Control Number 0910–0607—Extension

A guidance document entitled "Guidance for Administrative Procedures for CLIA Categorization" was released on May 7, 2008. The document describes procedures FDA uses to assign the complexity category to a device. Typically, FDA assigns complexity categorizations to devices at the time of clearance or approval of the device. In this way, no additional burden is incurred by the manufacturer because the labeling (including operating instructions) is included in the premarket notification (510(k)) or premarket approval application (PMA). In some cases, however, a manufacturer may request CLIA categorization even if FDA is not simultaneously reviewing a 510(k) or PMA. One example is when a manufacturer requests that FDA assign CLIA categorization to a previously cleared device that has changed names since the original CLIA categorization. Another example is when a device is exempt from premarket review. In such cases, the guidance recommends that manufacturers provide FDA with a copy of the package insert for the device and a cover letter indicating why the manufacturer is requesting a categorization (*e.g.* name change, exempt from 510(k) review). The guidance recommends that in the correspondence to FDA the manufacturer should identify the product code and classification as well as reference to the original 510(k) when this is available.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Request for CLIA Categorization	60	15	900	1	900	$46,800

[1] There are no capital costs associated with this collection of information.

The number of respondents is approximately 60. On average, each respondent will request categorizations (independent of a 510(k) or PMA) 15 times per year. The cost, not including personnel, is estimated at $52 per hour (52 × 900), totaling $46,800. This includes the cost of copying and mailing copies of package inserts and a cover letter, which includes a statement of the reason for the request and reference to the original 510(k) numbers, including regulation numbers and product codes. The burden hours are based on FDA familiarity with the types of documentation typically included in a sponsor's categorization requests, and costs for basic office supplies (*e.g.,* paper).

Dated: April 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–09769 Filed 4–26–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Office of Medical Products and Tobacco; Center for Drug Evaluation and Research; Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Medical Policy has modified its structure. This new organizational structure was approved by the Secretary of Health and Human Services on December 15, 2016, and effective on April 17, 2016.

FOR FURTHER INFORMATION CONTACT: Melanie Keller, Office of Management, Center for Drug Evaluation and Research, Office of Medical Products and Tobacco, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993, 301–796–3291.

I. Summary

This organization will expand current activities in the Office of Medical Policy and foster efficient oversight of clinical trials conducted through policy initiatives that build quality upfront and science-based inspectional approaches. This will provide an oversight and direction for new and ongoing policy initiatives in broad-based medical and clinical policy areas, including initiatives to improve science and efficiency trials.

The Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Medical Policy has been restructured as follows:

DKKNF. ORGANIZATION. The Office of Medical Policy is headed by the Director, Office of Medical Policy and includes the following organizational units:

Office of Medical Policy
Office of Prescription Drug Promotion
Division of Advertising and Promotion Review I
Division of Advertising and Promotion Review II

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guides (SMG). Persons interested in seeing the complete Staff Manual Guide can find it on FDA's Web site at: *http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm.*

Authority: 44 U.S.C. 3101.

Dated: April 19, 2016.

Sylvia M. Burwell,

Secretary of Health and Human Services.

[FR Doc. 2016–09761 Filed 4–26–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than June 27, 2016.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Building Futures: Supporting Youth Living with HIV OMB No. 0915–xxxx New.

Abstract: The Ryan White HIV/AIDS Program (RWHAP), administered by the HRSA HIV/AIDS Bureau (HRSA/HAB), provides HIV-related services in the United States for people living with HIV (PLWH) who do not have sufficient health care coverage or financial resources to pay for HIV-related services. Fourteen percent of the approximately 512,000 RWHAP clients in 2014 were young adults between the ages of 13 and 30.[1] HRSA/HAB has awarded a contract, *Building Futures: Supporting Youth Living with HIV,* to identify and document best-practices and challenges associated with providing HIV care to youth living with HIV. Information learned from high performing and low performing sites serving young people living with HIV (aged 13–24 years) will help identify effective strategies and barriers for helping this population reach viral suppression. The high performing and low performing sites will be chosen from RWHAP-funded providers based on health outcome data from the 2014 Ryan White HIV/AIDS Services Report. Information gathered at these visits will help inform technical assistance (TA) conducted at low performing sites, as well as additional TA products to be made available to other RWHAP providers to improve health outcomes for young people living with HIV.

Need and Proposed Use of the Information: Youth (defined for the purposes of this project as age 13 through 24) in the United States are disproportionately impacted by HIV. In 2014, 9,731 (22 percent) of the 44,073 new HIV diagnoses in the U.S. were among youth between the ages of 13 and 24, with a large majority (81 percent) of these youth diagnoses among older youth aged 20–24.[2] Young people living with HIV also experience disparities in outcomes along the HIV care continuum.[3] Among RWHAP clients in 2014, older youth aged 20–24 had the lowest rates of retention in care and both 15–19 year olds and 20–24 year olds had notably lower rates of viral load suppression as compared to other age groups. Additionally, certain subpopulations such as young men who have sex with men (MSM) of color, lesbian, gay, bisexual, transgender and questioning youth (LGBTQ), and young women of color bear a disproportionate share of the disease burden and have poorer outcomes in the areas of retention in care and viral suppression.[4] [5]

The *Building Futures: Supporting Youth Living with HIV* project aims to strengthen RWHAP engagement with young people aged 13–24 living with HIV to improve their health outcomes. Through this project, HRSA/HAB will systematically document strategies used by providers funded by the RWHAP to achieve high rates of youth retention in care and viral suppression. HRSA/HAB will also learn about gaps and challenges from providers that have demonstrated poorer outcomes in these areas.

Specialized Site Visits will be conducted with 10 high performing providers to identify, understand, and document replicable evidence-based best practices and models of care. Interviews will be conducted with program support and clinical staff, in addition to HIV-positive youth patients. HIV-positive youth leaders will be engaged as consultants to the site visit team to pretest instruments, review site visit conclusions with the project team, and offer a perspective of young people living with HIV on the data gathered from the high-performing sites and implementation of changes to improve performance of lower performing sites.

Performance Improvement Site Visits will be conducted with 16 lower performing providers to better understand the gaps and challenges to providing RWHAP care to youth, share best practices and lessons learned from high performing providers, and provide action-oriented TA to overcome barriers and optimize health outcomes. Youth consultants will co-lead a panel/advisory board of young people living with HIV and a planning session to better understand technical assistance implementation issues.

Sampled providers will be selected based on viral load and retention in care rates and the diversity of client populations, as identified in 2014 Ryan White HIV/AIDS Services Report data.

Likely Respondents: Clinics funded by the Ryan White HIV/AIDS Program.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (hours)	Total burden hours
Online Questionnaire	26	1	26	0.5	13
Onsite Observational Tool	26	1	26	0.5	13
Program Manager and Clinical Director Interview Guide (High) *	20	1	20	1.5	30
Program Manager and Clinical Director Interview Guide (Low) **	32	1	32	1.5	48

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[1] Health Resources and Services Administration. Ryan White HIV/AIDS Program Annual Client-Level Data Report 2014. *http://hab.hrsa.gov/data/servicesdelivered/2014RWHAPDataReport.pdf.* Published December 2015. Accessed 1/29/2016.

[2] Centers for Disease Control and Prevention, "Diagnoses of HIV Infection in the United States and Dependent Areas, 2014," HIV Surveillance Supplemental Report; Vol 26, November 2015, *http://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-us.pdf.*

[3] "HIV/AIDS Care Continuum," accessed January 26, 2016, *https://www.aids.gov/federal-resources/policies/care-continuum/.*

[4] Centers for Disease Control and Prevention, "HIV Among Youth," *HIV Among Youth,* June 30, 2015, *http://www.cdc.gov/hiv/group/age/youth/index.html.*

[5] "Youth and Young Adults in the Ryan White HIV/AIDS Program," September 2015, *http://hab.hrsa.gov/data/reports/youthdatareport2015.pdf.*

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (hours)	Total burden hours
Program and Administrative Staff Interview Guide (High) *	50	1	50	1	50
Program and Administrative Staff Interview Guide (Low) **	80	1	80	1	80
Youth Focus Group	156	1	156	1	156
Youth Interview	26	1	26	0.5	13
Panel/advisory board of young people living with HIV (Low) **	80	1	80	1.5	120
Total	496		496		523

* High indicates high performing sites.
** Low indicates low performing sites.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Jackie Painter,
Director, Division of Executive Secretariat.

[FR Doc. 2016–09772 Filed 4–26–16; 8:45 a.m.]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR must be received no later than May 27, 2016.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: HRSA AIDS Education and Training Centers Evaluation Activities

(OMB No. 0915–0281)—Revision

Abstract: The AIDS Education and Training Centers (AETC) Program, under the Title XXVI of the Public Health Service Act, as amended, supports a network of regional and national centers that conduct targeted, multi-disciplinary education and training programs for health care providers treating persons with HIV. The AETCs' purpose is to increase the number of health care providers who are effectively educated and motivated to counsel, diagnose, treat, and medically manage individuals with HIV infection, and to help prevent high risk behaviors that lead to HIV transmission.

Need and Proposed Use of the Information: As part of an ongoing effort to evaluate AETC activities, information is needed on AETC training sessions, consultations, and technical assistance activities. Each regional center collects information on AETC training events, and is required to report aggregate data on their activities to HRSA. The data provides information on the number of training events, including clinical trainings and consultations, as well as technical assistance activities conducted by each regional center, the number of health care providers receiving professional training or consultation, and the time and effort expended on different levels of training and consultation activities. In addition, information is obtained on the populations served by AETC trainees, and the increase in capacity achieved through training events. Collection of this information allows HRSA to provide information on training activities and types of education and training provided to Ryan White HIV/AIDS Program recipients, resource allocation, and capacity expansion.

Likely Respondents: Trainees are asked to complete the Participant Information Form once a year and trainers are asked to complete an Event Record for each training event they conduct during the year. In addition, each regional AETC (8 total) will compile these data into a data set and submit to HRSA once a year.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Participant Information	114,423	1	114,423	0.07	8,009.61
Event Record	14,445	1	14,445	0.14	2,022.30
Total					10,031.91

The Estimated Annual Burden to AETCs is as follows:

	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Aggregate Data Set	8	1	8	29	232

The total burden hours are 10,263.91 hours.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2016–09705 Filed 4–26–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting Announcement for the Physician-Focused Payment Model Technical Advisory Committee Required by the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015

ACTION: Notice of public meeting.

SUMMARY: This notice announces the meeting date for the Physician-Focused Payment Model Technical Advisory Committee (hereafter referred to as "the Committee") on Wednesday, May 4, 2016 in Washington, DC.

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DATES: The meeting will be held on Wednesday, May 4, 2016, from 12:00 p.m. to 3:00 p.m. Eastern Daylight Time (EDT) and it is open to the public.

ADDRESSES: The meeting will be held in Room 800 of the Hubert H. Humphrey Building, 200 Independence Ave. SW., Washington, DC, 20201.

Meeting Registration

The public may attend the meeting in-person or listen by phone via audio teleconference. Space is limited and registration is *required* in order to attend in-person or by phone. Registration may be completed online at *https://www.regonline.com/PTACMeetingsRegistration.* All the following information must be submitted when registering:

Name.

Company name.

Postal address.

Email address.

If sign language interpretation or other reasonable accommodation for a disability is needed, please contact Scott R. Smith, no later than April 25, 2016 at the contact information listed below.

FOR FURTHER INFORMATION CONTACT: Scott R. Smith, Ph.D., Designated Federal Officer, at the Office of Health Policy, Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, 200 Independence Ave. SW., Washington, DC 20201, (202) 690–6870.

SUPPLEMENTARY INFORMATION:

I. Purpose

The Physician-Focused Payment Model Technical Advisory Committee ("the Committee") is required by the Medicare Access and CHIP Reauthorization Act of 2015, 42 U.S.C 1395ee. This Committee is also governed by provisions of the Federal Advisory Committee Act, as amended (5 U.S.C App.), which sets forth standards for the formation and use of federal advisory committees. In accordance with its statutory mandate, the Committee is to review physician-focused payment model proposals and prepare recommendations regarding whether such models meet criteria that will be established through rulemaking by the Secretary of Health and Human Services (the Secretary). The Committee is composed of 11 members appointed by the Comptroller General with staggered terms of 1, 2, and 3 years.

II. Agenda

The Committee will have initial discussions about how physician-focused payment models proposals will be submitted and reviewed by the Committee after the Secretary establishes criteria for physician-focused payment models through rulemaking. There will be time allocated for public comment on a draft proposal review document. This document will be posted on the Committee Web site and distributed on the Committee listserv prior to the public meeting. The Committee will also discuss its activities in preparation for submission of proposals once the Secretarial criteria are finalized.

III. Meeting Attendance

The May 4, 2016 meeting is open to the public; however, in-person attendance is limited to space available. Priority to attend the meeting in-person will be given to those who pre-register. If the meeting venue reaches its seating capacity, other registrants will be limited to participating by telephone.

Persons wishing to attend this meeting, which is located on federal property, must register by following the instructions in the "Meeting Registration" section of this notice. A confirmation email will be sent to the registrants shortly after completing the registration process.

IV. Security and Building Guidelines

The following are the security and building guidelines:

Persons attending the meeting, including presenters, must be pre-registered and on the attendance list by the prescribed date.

Individuals who are not pre-registered in advance may not be permitted to enter the building and may be unable to attend the meeting.

Attendees must present a government-issued photo identification to the Federal Protective Service or Guard Service personnel before entering the building. Without a current, valid photo ID, persons may not be permitted entry to the building. All persons entering the building must pass through a metal detector.

All items brought into the Humphrey Building including personal items, for example, laptops and cell phones, are subject to physical inspection.

The public may enter the building 30 to 45 minutes before the meeting convenes.

V. Special Accommodations

Individuals requiring special accommodations must include the request for these services during registration.

VI. Copies of the Charter

The Secretary's Charter for the Physician-Focused Payment Model Technical Advisory Committee is available on the ASPE Web site at *https://aspe.hhs.gov/medicare-access-and-chip-reauthorization-act-2015.* Information about how to subscribe to the Committee's email listserv is found at *https://aspe.hhs.gov/contact-physician-focused-payment-model-technical-advisory-committee.*

Dated: April 8, 2016.

Richard G. Frank,

Assistant Secretary for Planning and Evaluation.

[FR Doc. 2016–09762 Filed 4–26–16; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Medicare Access and CHIP Reauthorization Act of 2015 (MACRA): Request for Information (RFI) Regarding Assessing Interoperability for MACRA; Corrections

AGENCY: Office of the National Coordinator for Health IT (ONC), HHS.

ACTION: Request for information; corrections.

SUMMARY: This document corrects an error in the request for information entitled "Office of the National Coordinator for Health Information Technology; Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Request for Information (RFI) Regarding Assessing Interoperability for MACRA."

DATES: This correction is effective on April 27, 2016.

FOR FURTHER INFORMATION CONTACT: Talisha Searcy, Office of Policy, Evaluation & Analysis, ONC, 202–205–8417, *talisha.searcy@hhs.gov*

Vaishali Patel, Office of Policy, Evaluation & Analysis, ONC, 202–603–1239, *vaishali.patel@hhs.gov*

SUPPLEMENTARY INFORMATION:

I. Background

Following the publication of **Federal Register** document 2016–08134 of April 8, 2016 (81 FR 20651), request for information (RFI) entitled "Office of the National Coordinator for Health Information Technology; Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Request for Information (RFI) Regarding Assessing Interoperability for MACRA," we identified an error in the final RFI. We summarize and correct this error in the "Summary of Errors" and "Corrections of Errors" sections below.

II. Summary of Errors

1. In the **ADDRESSES** section we failed to identify the ONC file code necessary for submission of comments.

III. Correction of Errors

1. On page 20651 change "refer to file code ONC xxxx" to "refer to file code ONC 2016–08134"

Dated: April 21, 2016.

Wilma Robinson,

Deputy Executive Secretary to the Department, Department of Health and Human Services.

[FR Doc. 2016–09842 Filed 4–26–16; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, U.S.C. Appendix 2, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP and the full meeting agenda will be posted on the SACHRP Web site at: *http://www.dhhs.gov/ohrp/sachrp/mtgings/index.html.*

DATES: The meeting will be held on Wednesday, May 18, 2016, from 8:30 a.m. until 5:00 p.m. and Thursday, May 19, 2016, from 8:30 a.m. until 4:30 p.m.

ADDRESSES: Fishers Lane Conference Center, Terrace Level, 5635 Fishers Lane, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Julia Gorey, J.D., Executive Secretary, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240–453–8141; fax: 240–453–6909; email address: *SACHRP@hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The meeting will open to the public at 8:30 a.m., on Wednesday, May 18, followed by opening remarks from Dr. Jerry Menikoff, Director, Office for Human Research Protections (OHRP), and Dr. Jeffrey Botkin, SACHRP Chair. OHRP staff will begin the meeting by presenting a summary of public comment received on the Notice of Proposed Rulemaking on Federal Policy for the Protection of Human Subjects. The Subpart A Subcommittee (SAS) will then present their draft work products, including considerations for single IRB review and minimal risk informed consent models. On Thursday, May 19, the Subcommittee on Harmonization (SOH) will present revisions to their recommendations on clustered randomized trials, the return of individual research results, and benchmarking.

SAS was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

SOH was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

The meeting will adjourn at 4:30 p.m. May 19, 2016. Time for public comment sessions will be allotted both days.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify one of the designated SACHRP points of contact at the address/phone number listed above at least one week prior to the meeting. Registration is required for participation in the on-site public comment session; individuals may register on the day of the meeting. Individuals who would like to submit written statements as public comment should email or fax their comments to SACHRP at *SACHRP@hhs.gov* at least five business days prior to the meeting. Note that public comment should be relevant to agenda topics.

Dated: April 21, 2016.

Julia Gorey,

Executive Secretary, Secretary's Advisory Committee on Human Research Protections, Office for Human Research Protections.

[FR Doc. 2016–09818 Filed 4–26–16; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Chronic Fatigue Syndrome Advisory Committee

AGENCY: Office of the Secretary, Office of the Assistant Secretary for Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services (DHHS) is hereby giving notice that a meeting of the Chronic Fatigue Syndrome Advisory Committee (CFSAC) will take place via webinar and will be open to the public.

DATES: The CFSAC webinar will be held on Tuesday, May 17, 2016 and Wednesday, May 18, 2016, from 12:00 p.m. until 5:00 p.m. (ET).

ADDRESSES: The meeting will be conducted via webinar. This will not be an in-person meeting.

FOR FURTHER INFORMATION CONTACT: Nancy C. Lee, M.D., Designated Federal Officer, Chronic Fatigue Syndrome Advisory Committee, Department of Health and Human Services, 200 Independence Avenue SW., Room 712E, Washington, DC 20201. Please direct all inquiries to *cfsac@hhs.gov.*

SUPPLEMENTARY INFORMATION: The CFSAC is authorized under 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended. The purpose of the CFSAC is to provide advice and recommendations to the Secretary of Health and Human Services (HHS), through the Assistant Secretary for Health (ASH), on issues related to myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS). The issues can include factors affecting access and care for persons with ME/CFS; the science and definition of ME/CFS; and broader public health, clinical, research, and educational issues related to ME/CFS.

The agenda for this meeting and call-in information will be posted on the CFSAC Web site *http://www.hhs.gov/advcomcfs/index.html.*

Thirty minutes of public comment via telephone will be scheduled for each day of the webinar. Individuals will have three minutes to present their comments. Priority will be given to individuals who have not provided public comment within the previous year. We are unable to place international calls for public comments. To request a time slot for public comment, please send an email to *cfsac@hhs.gov* by May 9, 2016. The email should contain the speaker's name and the phone number that will be used for public comment.

Individuals who would like for their testimony to be provided to the Committee members should submit a copy of the testimony prior to the meeting. It is preferred that the submitted testimony be prepared in digital format and typed using a 12-pitch typeface. It must not exceed 5 single-space pages and is preferred that the document be prepared in the MS Word format. Please note that PDF files, handwritten notes, charts, and photographs cannot be accepted. Materials submitted should not include sensitive personal information, such as social security number, birthdates, driver's license number, passport number, financial account number, or credit or debit card number. If you wish to remain anonymous the document must specify this. The Committee welcomes input on any topic related to ME/CFS.

Dated: April 21, 2016.

Nancy C. Lee,

Designated Federal Officer, Chronic Fatigue Syndrome Advisory Committee.

[FR Doc. 2016–09840 Filed 4–26–16; 8:45 am]

BILLING CODE 4150–42–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Interest Rate on Overdue Debts

Section 30.18 of the Department of Health and Human Services' claims collection regulations (45 CFR part 30) provides that the Secretary shall charge an annual rate of interest, which is determined and fixed by the Secretary of the Treasury after considering private consumer rates of interest on the date that the Department of Health and Human Services becomes entitled to recovery. The rate cannot be lower than the Department of Treasury's current value of funds rate or the applicable rate determined from the "Schedule of Certified Interest Rates with Range of Maturities" unless the Secretary waives interest in whole or part, or a different rate is prescribed by statute, contract, or repayment agreement. The Secretary of the Treasury may revise this rate quarterly. The Department of Health and Human Services publishes this rate in the **Federal Register**.

The current rate of 10.00%, as fixed by the Secretary of the Treasury, is certified for the quarter ended March 31, 2016. This rate is based on the Interest Rates for Specific Legislation, "National Health Services Corps Scholarship Program (42 U.S.C. 254o(b)(1)(A))" and "National Research Service Award Program (42 U.S.C. 288(c)(4)(B))." This interest rate will be applied to overdue debt until the Department of Health and Human Services publishes a revision.

Dated: April 15, 2016.

David C. Horn,

Director, Office of Financial Policy and Reporting.

[FR Doc. 2016–09758 Filed 4–26–16; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Human Resources; Medical Professionals Recruitment and Continuing Education Programs

Announcement Type: New Limited Competition Cooperative Agreement

Funding Announcement Number: HHS–2016–IHS–HPR–0001

Catalog of Federal Domestic Assistance Number: 93.970

Key Dates

Application Deadline Date: June 27, 2016

Review Date: July 5–8, 2016

Earliest Anticipated Start Date: July 15, 2016

Proof of Non-Profit Status Due Date: June 27, 2016

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting competitive cooperative agreement applications for the Medical Professionals Recruitment and Continuing Education Program. This program is authorized under: The Snyder Act, 25 U.S.C. 13. This program is described in the Catalog of Federal Domestic Assistance (CFDA) under 93.970.

Background

The mission of the IHS is to raise the physical, mental, social and spiritual health of American Indians and Alaska Natives (AI/AN) to the highest level. The IHS, an agency within the Department of Health and Human Services (HHS), is responsible for providing Federal health services to AI/AN. The provision of health services to members of Federally-recognized Tribes grew out of the special government-to-government relationship between the Federal Government and Indian Tribes. The IHS is the principal Federal health care provider and health advocate for Indian people and its mission is to raise their health status to the highest possible level. The IHS provides a comprehensive health service delivery system for approximately 2.3 million AI/AN who belong to 567 Federally recognized Tribes in 35 states.

Purpose

The purpose of this IHS cooperative agreement is to enhance medical professional recruitment and continuing education programs, services and activities for AI/AN people. The agency wants to facilitate continuing medical education for AI/AN physicians, through annual meetings and other venues that are culturally competent and sensitive. Another purpose is to recruit AI/AN health professionals to pursue jobs that serve AI/AN people and improve the health care delivery system. A third purpose is to provide opportunities for AI/AN youth to learn about the various Federal agencies and possible careers within the Federal Government that will result in a national mentoring program and creation of a pipeline for AI/AN youth into health careers. IHS will provide funds in the amount of $105,000 in the first year (Fiscal Year 2016 only) to be used to complete the following Fiscal Year 2016 activities:

- To support a national Native American youth conference, designed to expose high school students to health care careers, as well as prepare them for college with the goal of becoming health care providers.
- To offer freshman and sophomore undergraduate students educational workshops to help them explore and prepare them for health education and careers in health care and/or research.
- To offer junior and senior undergraduate students, preparing to apply for medical and health professions schools, educational opportunities designed to provide guidance regarding personal statement reviews, mock interviews, and mentorship on the admission process.

The purpose of the activities listed above is to increase the number of AI/AN youth pursuing careers in the health professions, thereby increasing the number of AI/AN medical professionals available to manage the chronic health challenges of AI/AN patients, including diabetes, hypertension, heart disease, and obesity.

Limited Competition Justification

Competition is limited to organizations with expertise in advancing the health of AI/AN people. This limitation is necessary in order for IHS to ensure that the training, education, and outreach provided through this award are provided in a culturally competent manner. Additionally, applicants must have experience hosting healthcare forums and meetings combining modern medicine and traditional health practices to enhance health care delivery to AI/AN communities. Through such experience, applicants should have existing relationships with stakeholders that will encourage attendance at the meeting funded through this award. Applicants must offer educational programs, services and activities specifically tailored to motivating AI/AN students to remain in the academic pipeline and to pursue a career in the health professions and/or biomedical research. Finally, applicants must have experience in providing leadership and programs in various care arenas affecting AI/AN, such as diabetes mellitus, human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS), domestic violence, and methamphetamine use, in order to address the most pressing healthcare needs of AI/AN communities.

Pre-Conference Grant Requirements: The awardee is required to comply with the "HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meeting Space, Food, Promotional Items, and Printing and Publications," dated December 16, 2013 ("Policy"), as applicable to conferences funded by grants and cooperative agreements. The Policy is available at *http://www.hhs.gov/grants/contracts/contract-policies-regulations/conference-spending/*

The awardee is required to:

Provide a separate detailed budget justification and narrative for each conference anticipated. The cost categories to be addressed are as follows: (1) Contract/Planner, (2) Meeting Space/Venue, (3) Registration Web site, (4) Audio Visual, (5) Speakers Fees, (6) Non-Federal Attendee Travel, (7) Registration Fees, (8) Other (explain in detail and cost breakdown). For additional questions please contact Nannette Bellini on 301–443–0049 or email at *Nannette.bellini@ihs.gov*

II. Award Information

Type of Award

Cooperative Agreement.

Estimated Funds Available

The total amount of funding identified for the current fiscal year (FY) 2016 is approximately $105,000. Individual award amounts are anticipated to be between $25,000 and $105,000. The amount of funding available for competing and continuation awards issued under this announcement are subject to the availability of appropriations and budgetary priorities of the Agency. The

IHS is under no obligation to make awards that are selected for funding under this announcement.

The funding amounts per FY for this three-year cooperative agreement are as follows:

- FY 2016 $105,000 ($80,000 to support activities to promote AI/AN youth in pursuing health related careers)
- FY 2017 $25,000
- FY 2018 $25,000

The total amount of funding for this three-year project period is $155,000.

Anticipated Number of Awards

One limited competition award will be issued under this program announcement.

Project Period

The project period will be for three (3) years and will run consecutively from June 15, 2016 to June 14, 2019.

Cooperative Agreement

Cooperative agreements awarded by the HHS are administered under the same policies as a grant. The funding agency (IHS) is required to have substantial programmatic involvement in the project during the entire award segment. Below is a detailed description of the level of involvement required for both IHS and the grantee. IHS will be responsible for activities listed under section A and the grantee will be responsible for activities listed under section B as stated:

Substantial Involvement Description for Cooperative Agreement

A. IHS Programmatic Involvement

(1) The IHS would like to support an annual meeting of AI/AN physicians and other health professionals. At least two IHS staff will be part of the planning committee for any meetings or training. They will work closely with the planning staff on all aspects of the meeting and training including development of the agenda, keynote speakers, and special educational sessions, etc. The IHS will also provide links to the applicant's Web site from the IHS Web site.

(2) IHS staff will also participate in any Federal meetings with HHS and AI/AN youth to help facilitate information about the various agencies and to encourage youth to consider careers within HHS. This will assist youth to become more knowledgeable about Federal programs and resources available to AI/AN communities.

(3) IHS Clinical Support Center (CSC) will provide a process for offering continuing education (CE) credits for the annual meeting participants. The CSC is accredited as a sponsor of CE by various medical professional organizations.

(4) IHS Division of Health Professions Support will share information on recruitment strategies and current program information with applicant's staff and members. This sharing and dialogue will enhance communications and improve efforts to reach out to more AI/AN physicians and medical professionals.

B. Grantee Cooperative Agreement Award Activities

(1) Provide overall coordination and management of the annual meeting of AI/AN physicians and other health professionals, including hosting the planning committee and setting up conference calls and meetings in preparation of the annual meeting.

(i) Manage registration and logistics for annual meeting.

(ii) Distribute flyers and brochures to promote the annual meeting.

(iii) Finalize the agenda and all materials.

(iv) Provide meeting information on applicant's Web site with links to IHS Web site.

(2) Implement a national Native American youth health careers conference, including organizing the planning committee and setting up conference calls and meetings in preparation for the conference.

(i) Manage registration and logistics for the conference.

(ii) Distribute flyers and brochures to promote the conference.

(iii) Finalize the agenda and all materials.

(3) Coordinate and implement educational workshops for freshman and sophomore undergraduate students to help them explore and prepare for careers in health care and/or research.

(4) Coordinate and implement educational workshops for junior and senior undergraduate students preparing to apply for medical and health professions schools. This workshop should help students with writing personal statements, conducting mock interviews, and providing mentorship on the admission process.

III. Eligibility Information

1. Eligibility

This new limited competition funding opportunity is limited to 501(c)(3) non-profit organizations. Proof of 501(c)(3) status must be provided. In addition, applicant organizations must meet the following criteria:

- Have as a core goal improving the health of AI/AN.
- Be committed to pursuing excellence in Native American health care by promoting education in the medical disciplines, honoring traditional health principles and restoring the balance of mind, body, and spirit.
- Offer educational programs, services, and activities that motivate AI/AN students to remain in the academic pipeline and to pursue a career in the health professions and/or biomedical research.
- Foster forums where modern medicine combines with traditional healing to enhance health care delivery to AI/AN communities.
- Provide leadership in various care arenas affecting AI/AN, such as diabetes mellitus, HIV/AIDS, domestic violence and methamphetamine use.

Note: Please refer to Section IV.2 (Application and Submission Information/Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required such as Tribal resolutions, proof of non-profit status, etc.

2. Cost Sharing or Matching

The IHS does not require matching funds or cost sharing for grants or cooperative agreements.

3. Other Requirements

If application budgets exceed the highest dollar amount outlined under the "Estimated Funds Available" section within this funding announcement, the application will be considered ineligible and will not be reviewed for further consideration. If deemed ineligible, IHS will not return the application. The applicant will be notified by email by the Division of Grants Management (DGM) of this decision.

Proof of Non-Profit Status

Organizations claiming non-profit status must submit proof. A copy of the 501(c)(3) Certificate must be received with the application submission by the Application Deadline Date listed under the Key Dates section on page one of this announcement.

Applicants submitting any of the above additional documentation after the initial application submission due date are required to ensure the information was received by the IHS by obtaining documentation confirming delivery (*i.e.*, FedEx tracking, postal return receipt, etc.).

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and detailed instructions for this announcement can be found at *http://www.Grants.gov* or *http://www.ihs.gov/dgm/funding/*.

Questions regarding the electronic application process may be directed to Mr. Paul Gettys at (301) 443–2114 or (301) 443–5204.

2. Content and Form Application Submission

The applicant must include the project narrative as an attachment to the application package. Mandatory documents for all applicants include:

- Table of contents.
- Abstract (one page) summarizing the project.
- Application forms:
  - ○ SF–424, Application for Federal Assistance.
  - ○ SF–424A, Budget Information—Non-Construction Programs.
  - ○ SF–424B, Assurances—Non-Construction Programs.
- Budget Justification and Narrative (must be single spaced and not exceed five pages).
- Project Narrative (must be single spaced and not exceed ten pages).
  - ○ Background information on the organization.
  - ○ Proposed scope of work, objectives, and activities that provide a description of what will be accomplished, including a one-page Timeframe Chart.
- 501(c)(3) Certificate (if applicable).
- Biographical sketches for all key personnel.
- Contractor/Consultant resumes or qualifications and scope of work.
- Disclosure of Lobbying Activities (SF–LLL).
- Certification Regarding Lobbying (GG–Lobbying Form).
- Copy of current Negotiated Indirect Cost (IDC) rate agreement (required) in order to receive IDC.
- Documentation of current Office of Management and Budget (OMB) Audit as required by 45 CFR part 75, subpart F or other required Financial Audit (if applicable).

Acceptable forms of documentation include:

- ○ Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or
- ○ Face sheets from audit reports. These can be found on the FAC Web site: *http://harvester.census.gov/sac/dissem/accessoptions.html?submit=Go+To+Database*.

Public Policy Requirements:

All Federal-wide public policies apply to IHS grants and cooperative agreements with exception of the discrimination policy.

Requirements for Project and Budget Narratives

A. Project Narrative: This narrative should be a separate Word document that is no longer than ten pages and must: Be single-spaced, be type written, have consecutively numbered pages, use black type not smaller than 12 characters per one inch, and be printed on one side only of standard size 8½″ x 11″ paper.

Be sure to succinctly address and answer all questions listed under the narrative and place them under the evaluation criteria (refer to Section V.1, Evaluation criteria in this announcement) and place all responses and required information in the correct section (noted below), or they will not be considered or scored. These narratives will assist the Objective Review Committee (ORC) in becoming familiar with the applicant's activities and accomplishments prior to this cooperative agreement award. If the narrative exceeds the page limit, only the first ten pages will be reviewed. The ten-page limit for the narrative does not include the work plan, standard forms, table of contents, budget, budget justifications, and/or other appendix items.

There are three parts to the narrative: Part A—Program Information; Part B—Program Planning and Evaluation; and Part C—Program Report. See below for additional details about what must be included in the narrative.

Part A: Program Information (4 Page Limitation)

Section 1: Needs.

Describe the applicant's organizational commitment and administrative infrastructure to support this agreement. Explain the previous planning activities for any conferences, annual meetings and other forums or programs for AI/AN physicians and other health professionals. Describe the relationship with the IHS and the capacity to support this work.

Part B: Program Planning and Evaluation (3 Page Limitation)

Section 1: Program Plans.

Describe any conferences, annual meetings and other forums or program plans for AI/AN physicians and health professionals in clear detail including the proposed timelines and activities. The purpose of the meeting would be to provide continuing education for physicians and other health professionals on topics to improve the health of AI/AN patients, families and communities. Describe the anticipated impact of the meeting as it relates to improving the health services for AI/AN. In addition, describe plans to develop a mentoring program and pipeline for recruiting more AI/AN youth into the medical professions. Describe the target audience and goals of such programs to increase the number of AI/AN physicians and health care professionals providing health services to the Native American population.

Section 2: Program Evaluation.

Describe fully and clearly the plans for evaluating the impact of an annual meeting of AI/AN physicians and other health care professionals with anticipated results. Describe the plans for mentoring programs and preparing more AI/AN youth to enter the medical professionals in the workforce.

Part C: Program Report (3 Page Limitation)

Section 1: Describe major accomplishments over the last 24 months as it relates to recruiting more AI/AN youth into the medical professions and continuing to provide continuing education opportunities (meetings, conferences) for AI/AN physicians and other medical professionals. Please identify and describe significant program achievements associated with improving the health of the AI/AN population. Provide a comparison of the actual accomplishments to the goals established for the project.

B. Budget Narrative: This narrative must include a line item budget with a narrative justification for all expenditures identifying reasonable and allowable costs necessary to accomplish the goals and objectives as outlined in the project narrative. Budget should match the scope of work described in the project narrative. The budget narrative should not exceed five pages.

3. Submission Dates and Times

Applications must be submitted electronically through Grants.gov by 11:59 p.m. Eastern Daylight Time (EDT) on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Any application received after the application deadline will not be accepted for processing, nor will it be given further consideration for funding. Grants.gov will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the electronic application process, contact

Grants.gov Customer Support via email to *support@grants.gov* or at (800) 518–4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays). If problems persist, contact Mr. Paul Gettys (*Paul.Gettys@ihs.gov*), DGM Grant Systems Coordinator, by telephone at (301) 443–2114 or (301) 443–5204. Please be sure to contact Mr. Gettys at least ten days prior to the application deadline. Please do not contact the DGM until you have received a Grants.gov tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

If the applicant needs to submit a paper application instead of submitting electronically through Grants.gov, a waiver must be requested. Prior approval must be requested and obtained from Mr. Robert Tarwater, Director, DGM, (see Section IV.6 below for additional information). The waiver must: (1) Be documented in writing (emails are acceptable), *before* submitting a paper application, and (2) include clear justification for the need to deviate from the required electronic grants submission process. A written waiver request must be sent to *GrantsPolicy@ihs.gov* with a copy to *Robert.Tarwater@ihs.gov.* Once the waiver request has been approved, the applicant will receive a confirmation of approval email containing submission instructions and the mailing address to submit the application. A copy of the written approval *must* be submitted along with the hardcopy of the application that is mailed to DGM. Paper applications that are submitted without a copy of the signed waiver from the Director of the DGM will not be reviewed or considered for funding. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Paper applications must be received by the DGM no later than 5:00 p.m., EDT, on the Application Deadline Date listed in the Key Dates section on page one of this announcement. Late applications will not be accepted for processing or considered for funding.

4. Intergovernmental Review

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions

- Pre-award costs are not allowable.
- The available funds are inclusive of direct and appropriate indirect costs.
- Only one grant/cooperative agreement will be awarded per applicant.
- IHS will not acknowledge receipt of applications.

6. Electronic Submission Requirements

All applications must be submitted electronically. Please use the *http://www.Grants.gov* Web site to submit an application electronically and select the "Find Grant Opportunities" link on the homepage. Download a copy of the application package, complete it offline, and then upload and submit the completed application via the *http://www.Grants.gov* Web site. Electronic copies of the application may not be submitted as attachments to email messages addressed to IHS employees or offices.

If the applicant receives a waiver to submit paper application documents, they must follow the rules and timelines that are noted below. The applicant must seek assistance at least ten days prior to the Application Deadline Date listed in the Key Dates section on page one of this announcement.

Applicants that do not adhere to the timelines for System for Award Management (SAM) and/or *http://www.Grants.gov* registration or that fail to request timely assistance with technical issues will not be considered for a waiver to submit a paper application.

Please be aware of the following:

- Please search for the application package in *http://www.Grants.gov* by entering the CFDA number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting your application electronically, please contact Grants.gov Support directly at: *support@grants.gov* or (800) 518–4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays).
- Upon contacting Grants.gov, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.
- If it is determined that a waiver is needed, the applicant must submit a request in writing (emails are acceptable) to *GrantsPolicy@ihs.gov* with a copy to *Robert.Tarwater@ihs.gov.* Please include a clear justification for the need to deviate from the standard electronic submission process.
- If the waiver is approved, the application should be sent directly to the DGM by the Application Deadline Date listed in the Key Dates section on page one of this announcement.
- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through Grants.gov as the registration process for SAM and Grants.gov could take up to fifteen working days.
- Please use the optional attachment feature in Grants.gov to attach additional documentation that may be requested by the DGM.
- All applicants must comply with any page limitation requirements described in this Funding Announcement.
- After electronically submitting the application, the applicant will receive an automatic acknowledgment from Grants.gov that contains a Grants.gov tracking number. The DGM will download the application from Grants.gov and provide necessary copies to the appropriate agency officials. Neither the DGM nor the Office of Human Resources will notify the applicant that the application has been received.
- Email applications will not be accepted under this announcement.

Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS)

All IHS applicants and grantee organizations are required to obtain a DUNS number and maintain an active registration in the SAM database. The DUNS number is a unique 9-digit identification number provided by D&B which uniquely identifies each entity. The DUNS number is site specific; therefore, each distinct performance site may be assigned a DUNS number. Obtaining a DUNS number is easy, and there is no charge. To obtain a DUNS number, please access it through *http://fedgov.dnb.com/webform,* or to expedite the process, call (866) 705–5711.

All HHS recipients are required by the Federal Funding Accountability and Transparency Act of 2006, as amended ("Transparency Act"), to report information on sub-awards. Accordingly, all IHS grantees must notify potential first-tier sub-recipients that no entity may receive a first-tier sub-award unless the entity has provided its DUNS number to the prime grantee organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

System for Award Management (SAM)

Organizations that were not registered with Central Contractor Registration and have not registered with SAM will need to obtain a DUNS number first and then access the SAM online registration through the SAM home page at *https://www.sam.gov* (U.S. organizations will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active). Completing and submitting the registration takes approximately one hour to complete and SAM registration will take 3–5 business days to process. Registration with the SAM is free of charge. Applicants may register online at *https://www.sam.gov.*

Additional information on implementing the Transparency Act, including the specific requirements for DUNS and SAM, can be found on the IHS Grants Management, Grants Policy Web site: *http://www.ihs.gov/dgm/policytopics/.*

V. Application Review Information

The instructions for preparing the application narrative also constitute the evaluation criteria for reviewing and scoring the application. Weights assigned to each section are noted in parentheses. The ten page narrative should include only the first year of activities; information for multi-year projects should be included as an appendix. See "Multi-year Project Requirements" at the end of this section for more information. The narrative section should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to understand the project fully. Points will be assigned to each evaluation criteria adding up to a total of 100 points. A minimum score of 75 points is required for funding. Points are assigned as follows:

1. Criteria

A. Introduction and Need for Assistance (30 points)

This section should include an understanding of the need for assistance and collaboration for any meetings or trainings. Applicant should demonstrate demographic and health status of the AI/AN people; geographic and social factors including availability of health providers and access to care; funding streams and available resources and partners that can support this work; and organizational structure of the Indian health system. Applicant should also describe the current and projected demand for AI/AN providers.

B. Project Objective(s), Work Plan and Approach (40 points)

This section should demonstrate the soundness and effectiveness of the applicant's proposal. Describe how the planning will be managed and the role of all organizations.

C. Program Evaluation (10 points)

This section should show how the progress on this project will be assessed and how the success of the recruitment program will be evaluated. Specifically, list and describe the outcomes by which the program will be evaluated. Identify the individuals responsible for evaluation of the annual meeting and their qualifications.

D. Organizational Capabilities, Key Personnel and Qualifications (10 points)

This section outlines the broader capacity of the organization to complete the project outlined in the work plan. It includes the identification of personnel responsible for completing tasks and the chain of responsibility for successful completion of the program outlined in the work plan.

(1) Describe the structure of the organization.

(2) Describe the ability of the organization to manage the proposed projects.

(3) List key personnel who will work on the projects and annual meeting. In the Appendix, include position descriptions and resumes of key staff and their duties and experience. Describe who will be writing progress reports.

E. Categorical Budget and Budget Justification (10 points)

This section should provide a clear estimate of the program costs and justification for expenses for the cooperative agreement period. The budget and budget justification should be consistent with the tasks identified in the work plan. If indirect costs are claimed, indicate and apply the current negotiated rate to the budget. Include a copy of the rate agreement in the appendix. Categorical budget (Form SF 424A) should be completed for each of the budget periods requested.

Multi-Year Project Requirements

Projects requiring a second, third, fourth, and/or fifth year must include a brief project narrative and budget (one additional page per year) addressing the developmental plans for each additional year of the project.

Additional Documents Can Be Uploaded as Appendix Items in Grants.gov

- Work plan, logic model and/or time line for proposed objectives.
- Position descriptions for key staff.
- Resumes of key staff that reflect current duties.
- Consultant or contractor proposed scope of work and letter of commitment (if applicable).
- Current Indirect Cost Agreement.
- Additional documents to support narrative (*i.e.* data tables, key news articles, etc.).

2. Review and Selection

Each application will be prescreened by the DGM staff for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the ORC based on evaluation criteria in this funding announcement. The ORC could be composed of both Tribal and Federal reviewers appointed by the IHS program to review and make recommendations on these applications. The technical review process ensures selection of quality projects in a national competition for limited funding. Incomplete applications and applications that are non-responsive to the eligibility criteria will not be referred to the ORC. The applicant will be notified via email of this decision by the Grants Management Officer of the DGM. Applicants will be notified by DGM, via email, to outline minor missing components (*i.e.,* budget narratives, audit documentation, key contact form) needed for an otherwise complete application. All missing documents must be sent to DGM on or before the due date listed in the email of notification of missing documents required.

To obtain a minimum score for funding by the ORC, applicants must address all program requirements and provide all required documentation.

VI. Award Administration Information

1. Award Notices

The Notice of Award (NoA) is a legally binding document signed by the Grants Management Officer and serves as the official notification of the grant award. The NoA will be initiated by the DGM in our grant system, GrantSolutions (*https://www.grantsolutions.gov*). Each entity that is approved for funding under this announcement will need to request or have a user account in GrantSolutions in order to retrieve their NoA. The NoA is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period.

Disapproved Applicants

Applicants who received a score less than the recommended funding level for approval (75) and were deemed to be disapproved by the ORC, will receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC outlining the strengths and weaknesses of their application submitted. The IHS program office will also provide additional contact information as needed to address questions and concerns as well as provide technical assistance if desired.

Approved But Unfunded Applicants

Approved but unfunded applicants that met the minimum scoring range and were deemed by the ORC to be "Approved", but were not funded due to lack of funding, will have their applications held by DGM for a period of one year. If additional funding becomes available during the course of FY 2016 the approved but unfunded application may be re-considered by the awarding program office for possible funding. The applicant will also receive an Executive Summary Statement from the IHS program office within 30 days of the conclusion of the ORC.

Note: Any correspondence other than the official NoA signed by an IHS Grants Management Official announcing to the project director that an award has been made to their organization is not an authorization to implement their program on behalf of IHS.

2. Administrative Requirements

Cooperative agreements are administered in accordance with the following regulations, policies, and OMB cost principles:

A. The criteria as outlined in this program announcement.

B. Administrative Regulations for Grants: CFR.

- Uniform Administrative Requirements HHS Awards, located at 45 CFR part 75.

C. Grants Policy:

- HHS Grants Policy Statement, Revised 01/07.

D. Cost Principles:

- Uniform Administrative Requirements for HHS Awards, "Cost Principles," located at 45 CFR part 75, subpart E.

E. Audit Requirements:

- Uniform Administrative Requirements for HHS Awards, "Audit Requirements," located at 45 CFR part 75, subpart F.

3. Indirect Costs

This section applies to all grant recipients that request reimbursement of indirect costs (IDC) in their grant application. In accordance with HHS Grants Policy Statement, Part II–27, IHS requires applicants to obtain a current IDC rate agreement prior to award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate covers the applicable grant activities under the current award's budget period. If the current rate is not on file with the DGM at the time of award, the IDC portion of the budget will be restricted. The restrictions remain in place until the current rate is provided to the DGM.

Generally, IDC rates for IHS grantees are negotiated with the Division of Cost Allocation (DCA) *https://rates.psc.gov/* and the Department of Interior (Interior Business Center) *https://www.doi.gov/ibc/services/finance/indirect-Cost-Services/indian-tribes.* For questions regarding the IDC policy, please call the Grants Management Specialist listed under "Agency Contacts" or the main DGM office at (301) 443–5204.

4. Reporting Requirements

The grantee must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports. Per DGM policy, all reports are required to be submitted electronically by attaching them as a "Grant Note" in GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please see the Agency Contacts list in section VII for the systems contact information.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required semi-annually, within 30 days after the budget period ends. These reports must include a brief comparison of actual accomplishments to the goals established for the period, a summary of progress to date or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final report must be submitted within 90 days of expiration of the budget/project period.

The final report for budget/project year one (FY 2016 only) should include:

- The date of the national Native American youth conference; number of high school student attendees; basic information regarding the agenda; and a summary of the results of attendee evaluations.
- The total number of workshops conducted for freshman and sophomore undergraduate students to help them explore and prepare for health education and careers in health care and/or research; number of attendees at each workshop; basic information regarding the agenda; and a summary of the results of attendee evaluations.
- The total number of workshops conducted for junior and senior undergraduate students preparing to apply to medical and health professions schools; number of attendees at each workshop; basic information regarding the agenda; and a summary of the results of attendee evaluations.

B. Financial Reports

Federal Financial Report FFR (SF–425), Cash Transaction Reports are due 30 days after the close of every calendar quarter to the Payment Management Services, HHS at: *http://www.dpm.psc.gov.* It is recommended that the applicant also send a copy of the FFR (SF–425) report to the Grants Management Specialist. Failure to submit timely reports may cause a disruption in timely payments to the organization.

Grantees are responsible and accountable for accurate information being reported on all required reports: The Progress Reports and Federal Financial Report (FFR).

C. Post Conference Grant Reporting

The following requirements were enacted in Section 3003 of the Consolidated Continuing Appropriations Act, 2013, and Section 119 of the Continuing Appropriations Act, 2014; *Office of Management and Budget Memorandum M–12–12:* All HHS/IHS awards containing grants funds allocated for conferences will be required to complete a mandatory post award report for all conferences. Specifically: The total amount of funds provided in this award/cooperative agreement that were spent for "Conference X", must be reported in final detailed actual costs *within 15 days of the completion of the conference.* Cost categories to address should be: *(1) Contract/Planner, (2) Meeting Space/Venue, (3) Registration Web site, (4) Audio Visual, (5) Speakers Fees, (6) Non-Federal Attendee Travel, (7) Registration Fees, (8) Other.*

D. Federal Sub-Award Reporting System (FSRS)

This award may be subject to the Transparency Act sub-award and executive compensation reporting requirements of 2 CFR part 170.

The Transparency Act requires the OMB to establish a single searchable database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal grants to report information about first-tier sub-awards and executive compensation under Federal assistance awards.

IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a $25,000 sub-award obligation dollar threshold met for any specific reporting period. Additionally, all new (discretionary) IHS awards (where the project period is made up of more than one budget period) and where: (1) The project period start date was October 1, 2010 or after and (2) the primary awardee will have a $25,000 sub-award obligation dollar threshold during any specific reporting period will be required to address the FSRS reporting. For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Policy Web site at: *http://www.ihs.gov/dgm/policytopics/.*

E. Compliance With Executive Order 13166 Implementation of Services Accessibility Provisions for All Grant Application Packages and Funding Opportunity Announcements

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see *http://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/guidance-federal-financial-assistance-recipients-title-VI/.*

The HHS Office for Civil Rights also provides guidance on complying with civil rights laws enforced by HHS. Please see *http://www.hhs.gov/civil-rights/for-individuals/section-1557/index.html;* and *http://www.hhs.gov/civil-rights/index.html.* Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see *http://www.hhs.gov/civil-rights/for-individuals/disability/index.html.* Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at *http://www.hhs.gov/civil-rights/for-individuals/disability/index.html* or call 1–800–368–1019 or TDD 1–800–537–7697. Also note it is an HHS Departmental goal to ensure access to quality, culturally competent care, including long-term services and supports, for vulnerable populations. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at *http://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53.*

Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of his/her exclusion from benefits limited by federal law to individuals eligible for benefits and services from the Indian Health Service.

Recipients will be required to sign the HHS–690 Assurance of Compliance form which can be obtained from the following Web site: *http://www.hhs.gov/sites/default/files/forms/hhs-690.pdf,* and send it directly to the: U.S. Department of Health and Human Services, Office of Civil Rights, 200 Independence Ave. SW., Washington, DC 20201.

F. Federal Awardee Performance and Integrity Information System (FAPIIS)

The IHS is required to review and consider any information about the applicant that is in the Federal Awardee Performance and Integrity Information System (FAPIIS) before making any award in excess of the simplified acquisition threshold (currently $150,000) over the period of performance. An applicant may review and comment on any information about itself that a federal awarding agency previously entered. IHS will consider any comments by the applicant, in addition to other information in FAPIIS in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed by applicants as described in 45 CFR 75.205.

As required by 45 CFR part 75 Appendix XII of the Uniform Guidance, non-federal entities (NFEs) are required to disclose in FAPIIS any information about criminal, civil, and administrative proceedings, and/or affirm that there is no new information to provide. This applies to NFEs that receive federal awards (currently active grants, cooperative agreements, and procurement contracts) greater than $10,000,000 for any period of time during the period of performance of an award/project.

Mandatory Disclosure Requirements

As required by 2 CFR part 200 of the Uniform Guidance, and the HHS implementing regulations at 45 CFR part 75, effective January 1, 2016, the IHS must require a non-federal entity or an applicant for a federal award to disclose, in a timely manner, in writing to the IHS or pass-through entity all violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award.

Submission is required for all applicants and recipients, in writing, to the IHS and to the HHS Office of Inspector General all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. 45 CFR 75.113

Disclosures must be sent in writing to:

U.S. Department of Health and Human Services, Indian Health Service, Division of Grants Management, ATTN: Robert Tarwater, Director, 5600 Fishers Lane, Mail Stop 09E70, Rockville, Maryland 20857.

(Include "Mandatory Grant Disclosures" in subject line)

Ofc: (301) 443–5204
Fax: (301) 594–0899
Email: Robert.Tarwater@ihs.gov

AND

U.S. Department of Health and Human Services, Office of Inspector General, ATTN: Mandatory Grant

Disclosures, Intake Coordinator, 330 Independence Avenue SW., Cohen Building, Room 5527, Washington, DC 20201. URL: *http://oig.hhs.gov/fraud/report-fraud/index.asp.*

(Include "Mandatory Grant Disclosures" in subject line)

Fax: (202) 205–0604 (Include "Mandatory Grant Disclosures" in subject line) or.

Email: *MandatoryGranteeDisclosures@oig.hhs.gov.*

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371 Remedies for noncompliance, including suspension or debarment (See 2 CFR parts 180 and 376 and 31 U.S.C. 3321).

VII. Agency Contacts

1. Questions on the programmatic issues may be directed to: Susan Karol, M.D., Chief Medical Officer, 5600 Fishers Lane, Mail Stop: 08E53, Rockville, MD 20857, *Phone:* 301–443–1083, *Fax:* 301–443–4794, *Email: Susan.Karol@ihs.gov.*

2. Questions on grants management and fiscal matters may be directed to: Ms. Cherron Smith, Grants Management Specialist, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, *Phone:* 301–443–5204, *Fax:* 301–443–9602, *Email: Cherron.Smith@ihs.gov.*

3. Questions on systems matters may be directed to: Paul Gettys, Grant Systems Coordinator, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, *Phone:* 301–443–2114; or the DGM main line 301–443–5204, *Fax:* 301–443–9602. *Email: Paul.Gettys@ihs.gov.*

VIII. Other Information

The Public Health Service strongly encourages all cooperative agreement and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Dated: April 20, 2016.

Elizabeth A. Fowler,

Deputy Director for Management Operations, Indian Health Service.

[FR Doc. 2016–09812 Filed 4–26–16; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Time-Sensitive Obesity.

Date: June 1, 2016.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7353, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–8898, *barnardm@extra.niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RFA–DK–15–019: Research using Biosamples and Subjects from Type 1 Diabetes Clinical Studies—Complications (DP3).

Date: June 3, 2016.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Dianne Camp, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7013, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, 301–594–7682, *campd@extra.niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Roles of Brown and Beige Adipose Tissue in Humans (R01).

Date: June 22, 2016.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Jian Yang, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7111, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7799, *yangj@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: April 21, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–09740 Filed 4–26–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: Automated Explanation and Hypothesis Generation at the Genome Scale.

Date: May 25, 2016.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Mark Caprara, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5156, MSC 7844, Bethesda, MD 20892, 301–435–1042, *capraramg@mail.nih.gov.*

Name of Committee: Cell Biology Integrated Review Group; Nuclear and Cytoplasmic Structure/Function and Dynamics Study Section.

Date: May 26–27, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Fisherman's Wharf Hotel, 2500 Mason Street, San Francisco, CA 94133.

Contact Person: David Balasundaram, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5189, MSC 7840, Bethesda, MD 20892, 301–435–1022, *balasundaramd@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowship: Surgical Sciences Biomedical Imaging and Bioengineering.

Date: May 26, 2016.

Time: 10:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jan Li, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5106, Bethesda, MD 20892, 301.402.9607, *Jan.Li@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; EB16–002: Neuroimaging Informatics Tools and Resources Clearinghouse.

Date: May 26, 2016.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Yvonne Bennett, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5199, MSC 7846, Bethesda, MD 20892, 301–379–3793, *bennetty@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 21, 2016.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–09738 Filed 4–26–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; Quantum Review Meeting (2016/10).

Date: June 7, 2016.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, Suite 920, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: John K. Hayes, Ph.D., Scientific Review Officer, 6707 Democracy Blvd., Suite 959, Democracy Two, Bethesda, MD 20892, (301) 451–3398, *hayesj@mail.nih.gov.*

Dated: April 21, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–09739 Filed 4–26–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Mental Health Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Mental Health Council.

Date: May 26, 2016.

Open: 9:00 a.m. to 1:00 p.m.

Agenda: Presentation of the NIMH Director's Report and discussion of NIMH program and policy issues.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Closed: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Jean G. Noronha, Ph.D., Director, DEA, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6154, MSC 9609, Bethesda, MD 20892–9609, 301–443–3367, *jnoronha@mail.nih.gov.*

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/index.shtml.,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: April 21, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–09741 Filed 4–26–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Mammalian Models for Translational Research.

Date: May 19, 2016.

Time: 12:30 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Lambratu Rahman Sesay, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, 301–451–3493, *rahmanl@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–PM–16–003: Precision Medicine Initiative Cohort Program Participant Technologies Center (U24).

Date: May 23, 2016.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Wenchi Liang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3150, MSC 7770, Bethesda, MD 20892, 301–435–0681, *liangw3@csr.nih.gov.*

Name of Committee: Emerging Technologies and Training Neurosciences Integrated Review Group; Bioengineering of Neuroscience, Vision and Low Vision Technologies Study Section.

Date: May 24–25, 2016.

8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Marriott Georgetown, 1221 22nd Street NW., Washington, DC 20037.

Contact Person: Robert C Elliott, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5190, MSC 7846, Bethesda, MD 20892, 301–435–3009, *elliotro@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Animal Models and Stem Cell-based Therapies for Regenerative Medicine.

Date: May 25, 2016.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jonathan Arias, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5170, MSC 7840, Bethesda, MD 20892, 301–435–2406, *ariasj@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 21, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–09737 Filed 4–26–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Automated Commercial Environment (ACE); Announcement of National Customs Automation Program Test of the In-Transit Manifest Pilot Program

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: General notice.

SUMMARY: This document announces that U.S. Customs and Border Protection (CBP) plans to conduct a National Customs Automation Program (NCAP) test relating to truck shipments of commercial goods that transit from a point of origination in Canada through the United States to a point of destination in Canada. Under the NCAP test, CBP will use a new filing code to identify shipments as being part of the In-Transit Manifest Pilot Program in CBP's Automated Commercial Environmental (ACE) Truck Manifest System. Test participants will submit electronically an in-transit manifest with a relaxed validation for the value data element and they will not have to provide the Harmonized Tariff Schedule (HTS) number. This notice provides a description of the NCAP test and specifies the duration and locations of the test. It also invites public comment on any aspect of the test.

DATES: The test will commence no earlier than May 27, 2016 and will run for approximately six months at the following ports: Port Huron, Michigan; Pembina, North Dakota; and Blaine, Washington. Comments concerning this notice and all aspects of the announced test may be submitted at any time during the test period.

ADDRESSES: Written comments concerning program, policy and technical issues should be submitted to Manuel Garza, Director, Manifest and Conveyance Security Division, U.S. Customs and Border Protection, via email at *manuel.a.garza@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. CBP Regulations

Under CBP regulations, a truck with merchandise that transits the United States during a trip that originates and terminates in Canada must present a paper manifest form, the United States-Canada Transit Manifest, known as Customs Form 7512–B Canada 8½, to CBP when it crosses the border at the U.S. ports of arrival and exit. The procedures for these in-transit shipments are addressed in 19 CFR 123.42 (Truck shipments transiting the United States). Among other things, the regulation provides that trucks transiting the United States must be sealed at the U.S. port of arrival. The regulation also provides that merchandise transported in trucks shall be forwarded in accordance with the general provisions for transportation in-bond (19 CFR 18.1–18.8).

In addition to the requirement to present a paper manifest when a truck crosses the border, CBP also requires electronic filing of certain information regarding the cargo carried by a truck in advance of the truck's arrival at the border. Under 19 CFR 123.92(a), with a few exceptions, for any inbound truck required to report its arrival under 19 CFR 123.1(b) that will have commercial cargo aboard, CBP must electronically receive certain information regarding the cargo to a CBP-approved EDI system [1] no later than either 30 minutes [2] or one hour prior to the

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[1] In a notice published in the **Federal Register** on October 27, 2006 (71 FR 62922), CBP designated the ACE Truck Manifest System as the approved EDI for the transmission of required data and announced that the requirement to transmit advance electronic cargo information through ACE would be phased in by groups of ports-of-entry. Through a series of **Federal Register** notices published from the October 27, 2006 notice and concluding with a November 13, 2007 notice (72 FR 63805), CBP mandated the use of ACE for the transmission of advance electronic truck cargo information at all land border ports-of-entry.

[2] As explained in the preamble of the final rule implementing section 123.92, published in the **Federal Register** on December 5, 2003 (68 FR 68140), the 30 minute timeframe applies to truck carriers arriving with shipments qualified for

Continued

carrier's reaching the first port of arrival in the United States. This includes cargo arriving by truck for transportation through the United States from one point to another in the same foreign country.

Truck carriers have been providing up to 69 data elements (including 1 optional data element) as part of their e-Manifest in the ACE Truck Manifest System, as a result of prior NCAP tests performed in conjunction with the Federal Motor Carrier Safety Administration. *See* 69 FR 55167 (September 13, 2004) and 70 FR 13514 (March 21, 2005) and related test notices identified therein. For the purposes of this test, the same data elements will be required, except as otherwise provided for in this notice. The ACE Truck Manifest System enables truck carriers with merchandise transiting the United States from point to point in Canada to file an e-Manifest and enter the merchandise as a Transportation & Exportation (T&E) in-bond entry.

B. Beyond the Border Initiative

On February 4, 2011, President Obama and Prime Minister Harper announced the United States-Canada joint declaration, *Beyond the Border: A Shared Vision for Perimeter Security and Economic Competitiveness* ("Beyond the Border"). Beyond the Border articulates a shared approach to security in which both countries work together to address threats within, at, and away from the U.S.-Canada border, while expediting lawful trade and travel.

On December 7, 2011, President Obama and Prime Minister Harper released the Beyond the Border Action Plan, which sets out joint priorities and specific initiatives for achieving this vision. The Beyond the Border Action Plan proposed a number of pilot projects to test new approaches to facilitating the secure movement of goods, including a U.S. pilot that would involve "the testing of a new in-bond module for processing in-transit/in-bond (Canada-United States-Canada) cargo traveling by truck." *See* Beyond the Border Action Plan (December 7, 2011). CBP is conducting this NCAP test to assess a new automated process for in-transit shipments in the ACE Truck Manifest System.

II. Authorization for the NCAP Test

The National Customs Automation Program (NCAP) was established in Subtitle B of Title VI—Customs Modernization, in the North American Free Trade Agreement Implementation Act (Pub. L. 103–182, 107 Stat. 2057, 2170, December 8, 1993) (Customs Modernization Act). *See* 19 U.S.C. 1411. The Customs Modernization Act provides the Commissioner of CBP with authority to conduct limited test programs or procedures designed to evaluate planned components of the NCAP. The NCAP test of In-Transit Manifest Pilot Program (referred to hereafter as "the NCAP test" or "the test") is authorized pursuant to 19 CFR 101.9(b) which provides for the testing of NCAP programs or procedures. *See* T.D. 95–21.

III. In-Transit Manifest Pilot Program

This notice announces CBP's In-Transit Manifest Pilot Program to test a new electronic in-transit manifest in the ACE Truck Manifest System. The details are provided below.

A. Description of Test

The NCAP test applies to the transportation of commercial cargo from a point of origination in Canada through the United States to a point of destination in Canada (CAN-US-CAN in-transit shipments). These shipments are essentially domestic Canadian shipments that transit through the United States. Under the test, participating truck carriers transporting cargo in CAN-US-CAN in-transit shipments will be required to submit an e-Manifest in the ACE Truck Manifest System no later than 30 minutes[3] prior to arrival in the United States under a new filing type code for these in-transit shipments. Participating carriers must submit an e-Manifest to CBP using the ANSI X12 format or the ACE Secure Data Portal. Participating carriers will not be required to submit the paper manifest form, Customs Form 7512–B Canada 8½, that is required under 19 CFR 123.42. Participating carriers are still required to submit the paper manifest form required under Canadian law to Canadian ports of entry.

Currently, CAN-US-CAN in-transit shipments are filed under shipment release type 62 as Transportation & Exportation (T&E) in-bond entries, which includes a complete ANSI X12 manifest (referred to as a 309 manifest) with the following information: Trip, shipment (including the value of the merchandise and the Harmonized Tariff Schedule (HTS) number), conveyance, equipment, crew and passenger data. Under the test, a new shipment release type 70 for CAN-US-CAN in-transit shipments will be used by participating carriers. Under shipment release type 70, participating carriers will be required to submit the same set of data elements as a 309 manifest but with a relaxed validation for the value data element. They will not be required to provide the HTS number.

For the value data element, CBP will accept a value amount of $2 per pound when the actual value is not available. With regard to the HTS number, an e-Manifest filed under shipment release type 62 requires an HTS number to the 6-digit level under which the cargo will be classified and a description of the cargo. For an e-Manifest filed by test participants under shipment release type 70, only a precise description of the cargo will be required.

Trade associations for Canadian trucking companies have identified these two data elements—value and the HTS number—as being the most problematic for CAN-US-CAN in-transit shipments. Canadian truck carriers rarely know the value and/or the exact HTS classification number for such in-transit cargo and in practice often file incorrect data when filing an e-Manifest under shipment release type 62. By relaxing the validation for the value data and removing the HTS number requirement, CBP intends to reduce the reporting burden on the industry and improve trade efficiencies between Canada and the United States.

The in-transit manifest will be processed and retained in ACE in the same manner as a type 62 manifest. Upon arrival in the United States, CBP will generate a "transit movement authorized" message (referred to as a 350 message) that will be sent to the carrier. The shipment will then be able to transit the United States and proceed to the United States port of export as an in-transit entry. When the shipment arrives at the United States port of export, the carrier will report the arrival of the shipment to CBP via an EDI message or through the carrier's ACE portal account. CBP will issue another 350 message to the carrier notifying the carrier that the shipment has entered Canada and that the in-transit entry is closed.

Requiring participating carriers to file an in-transit manifest electronically under new shipment release type 70, along with relaxing the validation for

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clearance under the FAST (Free and Secure Trade) Program. The FAST program is a cooperative effort between CBP and the governments of Canada and Mexico which provides expedited border processing for known, low-risk commercial drivers at the U.S.-Canada and U.S.-Mexico borders.

[3] Thirty minutes is the time-frame specified in 19 CFR 123.92(a) that applies to truck carriers using FAST commercial drivers. This is the applicable time-frame for participating truck carriers because as a condition of participation in this test, each carrier must use commercial drivers cleared under the FAST program. *See* part III.B of this notice.

the value data element and eliminating the HTS number requirement, will facilitate the in-transit manifest process for both the trade and CBP. Canadian carriers will be able to route certain domestic shipments through the United States with greater efficiency and CBP will benefit from an entirely electronic in-transit manifest.

B. Test Participants and Conditions of Participation

Participation in the In-Transit Manifest Pilot Program is currently limited to nine Canadian truck carriers that have been selected by CBP in consultation with the Canadian Border Services Agency (CBSA). Each participating carrier is a bonded carrier and a certified member of the Customs-Trade Partnership Against Terrorism (C–TPAT), a voluntary supply chain security program led by CBP that is focused on improving the security of private companies' supply chains with respect to terrorism. As a condition of participation, each carrier must use commercial drivers cleared under the FAST program. FAST driver identification provides CBP with a full set of identifying information regarding the driver, including the driver's name, date of birth, gender, citizenship, and address. Another condition of participation in this NCAP test is that no passengers are permitted on the Canadian trucks transiting the United States, with the exception of additional drivers also cleared under the FAST program. As provided in Section VI, participants are also required to take part in an evaluation of the test.

C. Test Duration and Locations

The NCAP test will be conducted for approximately six months from its start at the following ports of entry: Port Huron, Michigan; Pembina, North Dakota; and Blaine, Washington. Any future expansion of this NCAP test to additional ports and/or extension of the time period will be announced on CBP's Web site at *www.cbp.gov.* Participants will also be notified of any expansion.

IV. Regulatory Provisions Affected

Regulations in 19 CFR parts 18 and 123 that conflict with the terms and conditions of the NCAP test are suspended and overridden to the extent of the conflict for the duration of the test for test participants and only to the extent of their participation in this test.

V. Misconduct

If a test participant fails to abide by the rules, procedures, or term and conditions of this and all other applicable **Federal Register** notices, fails to exercise reasonable care in the execution of participant obligations, or otherwise fails to comply with all applicable laws and regulations, then the participant may be suspended from participation in this test and/or subjected to penalties, liquidated damages, and/or other administrative or judicial sanction. Additionally, CBP has the right to suspend a test participant based on a determination that an unacceptable compliance risk exists. Any decision proposing suspension may be appealed in writing to the Assistant Commissioner (Office of Field Operations) within 15 days of the decision date. Such proposed suspension will apprise the participant of the facts or conduct warranting suspension. Should the participant appeal the notice of proposed suspension, the participant should address the facts or conduct charges contained in the notice and state how he has or will achieve compliance. However, in the case of willfulness or where public health interests are concerned, the suspension may be effective immediately.

VI. Test Evaluation Criteria

All interested parties are invited to comment on any aspect of this test at any time. To ensure adequate feedback, participants are required to take part in an evaluation of this test. CBP needs comments and feedback on all aspects of this test, including the design, conduct and implementation of the test in order to determine whether to modify, alter, expand, limit, continue, end or implement this program by regulation. The final results of the evaluation will be published in the **Federal Register** and the Customs Bulletin as required by 19 CFR 101.9.

VII. Paperwork Reduction Act

As noted above, CBP is accepting only nine participants in the NCAP test. This means that fewer than ten persons will be subject to any information collections under the NCAP test. Accordingly, collections of information encompassed within this notice are exempted from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3502 and 3507).

Dated: April 22, 2016.

Todd Owen,

Assistant Commissioner, Office of Field Operations.

[FR Doc. 2016–09858 Filed 4–26–16; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

DEPARTMENT OF AGRICULTURE

Forest Service

Notice of Intent to prepare a Joint Environmental Impact Statement and To Conduct Public Scoping

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security and Forest Service, USDA.

ACTION: Notice of intent to prepare a Joint Environmental Impact Statement concerning the repair and maintenance of Bog Creek Road and closure of certain roads within the Blue-Grass Bear Management Unit in the Selkirk Mountains in Boundary County, Idaho; request for comments; and notice of public scoping.

SUMMARY: This notice announces that U.S. Customs and Border Protection (CBP) and the U.S. Forest Service (Forest Service) Idaho Panhandle National Forests (IPNF) (collectively the "Agencies") intend to prepare a joint Environmental Impact Statement (EIS) to identify and assess potential impacts upon the environment of: Repairing and maintaining an approximately 5.6-mile section of the existing Bog Creek Road, which is located in the Selkirk Mountains in Boundary County, Idaho, within approximately two miles of the Canadian border, on land within the Blue-Grass Bear Management Unit (BMU) that is managed by the IPNF; and closing for motorized use additional roads within the Blue-Grass BMU to comply with the IPNF *Forest Plan Amendments for Motorized Access Management within the Selkirk and Cabinet-Yaak Grizzly Bear Recovery Zones* (Access Amendment) and reduce road density in the Blue-Grass BMU. This notice initiates the public scoping process for the preparation of the EIS. The purpose of the public scoping process is to solicit public comments regarding the potential environmental impacts that may be addressed. This notice commences the public scoping period for which CBP and IPNF are requesting written comments. This process is being conducted pursuant to the National Environmental Policy Act (NEPA), the Council on Environmental Quality Regulations for Implementing the NEPA (40 CFR parts 1500–1508), and CBP and Forest Service NEPA guidelines. Additionally, pursuant to Section 106 of the National Historic Preservation Act, the public scoping

process will allow members of the general public to provide CBP and IPNF comments on potential impacts to historic and cultural resources for the proposed action.

DATES: The scoping comment period will be 30 days. To ensure consideration, comments must be received by May 27, 2016.

Comments may be submitted as set forth in the **ADDRESSES** section of this document. This project implements a land management plan and is subject to 36 CFR part 218, subparts A and B of the Forest Service's Project-level Predecisional Administrative Review Process. Pursuant to 36 CFR part 218, only those who provide specific, written comments regarding the proposed project will be eligible to file an objection.

ADDRESSES: Comments may be submitted either by mail or by email at the addresses indicated below. To avoid duplication, please use only one of the following methods to provide written comments:

(a) *Via mail:* Bog Creek Road EIS, P.O. Box 643, Flagstaff, Arizona, 86002–0643.

(b) *Via email: SPWBogCreekEIS@cbp.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Paul Enriquez, CBP, Border Patrol Facilities & Tactical Infrastructure Program Management Office, by telephone at (949) 643–6365, or by email at *Paul.Enriquez@cbp.dhs.gov.* You may also visit the CBP public Web site for more information at: *http://www.cbp.gov/about/environmental-cultural-stewardship/nepa-documents/docs-review.* Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Background

Repairs and Maintenance to Bog Creek Road

U.S. Customs and Border Protection (CBP) protects the nation's borders from terrorism, human and drug smuggling, illegal migration, and agricultural pests while facilitating the flow of legitimate travel and trade. CBP does so by integrating modern technology, deploying highly trained law enforcement personnel, and developing public and private sector partnerships that advance its overall mission.

At 5,500 miles in length, the Northern Border of the United States stands as the longest common border in the world. The terrain ranges from densely forested lands on the west and east coasts to open plains in the middle of the country. To complement its efforts, CBP uses partnerships with other Federal, state, and local law enforcement agencies to meet the challenges of ensuring security while facilitating legitimate trade and travel along this expansive and complex border area.

The primary road that provides east-west access to the Northern Border in the Selkirk Mountains of Northern Idaho is Bog Creek Road. Bog Creek Road is situated on National Forest System lands that are a part of the Idaho Panhandle National Forests (IPNF). The area is managed by the IPNF unit of the Forest Service (also referred to as IPNF). The road is currently impassable to most vehicles.

Bog Creek Road was closed on both ends in the late 1980s, to meet grizzly bear habitat requirements. As a result of the closure, the road has only been maintained on a limited basis. By the mid-1990s, the road had experienced minor failures. Around the year 2000, a large failure occurred when a large culvert failed due to heavy surface water runoff. At that time, the road became impassable to most vehicles. Currently, the road is gated at the east end and barricaded at the west end. In recent years, the road has been infrequently used by Forest Service and CBP personnel traveling on all-terrain vehicles (ATVs) and horseback, but using ATVs requires a winch system to traverse the large culvert failure. Nearly the entire length of Bog Creek Road is now overgrown with alder brush, small trees, and other vegetation.

Without access to the Northern Border area via Bog Creek Road, CBP must use a lengthy detour to get to the border, including using state highways in Washington and Idaho and other forest roads. This alternative route is approximately 180 miles and adds approximately four hours one way (eight hours total) to CBP patrol response times.

Closing Additional Roads for Motorized Use

Bog Creek Road is located within the Blue-Grass Bear Management Unit (BMU) of the Selkirk Grizzly Bear Recovery Zone (SRZ) of the IPNF. The IPNF has been working since the late 1980s to create secure habitat for grizzly bears. For example, Bog Creek Road was closed in the late 1980s to allow for more effective management of grizzly bear habitat. The IPNF continues to manage habitat conditions of the SRZ. To further manage grizzly bear habitat conditions, in 2011, the IPNF issued a Record of Decision (ROD) for the *Forest Plan Amendments for Motorized Access Management within the Selkirk and Cabinet-Yaak Grizzly Bear Recovery Zones* (Access Amendment). The Access Amendment set motorized vehicle access and security standards in the zones to conserve and contribute to the recovery of grizzly bears, and to meet the agency's responsibilities under the Endangered Species Act (ESA). These standards limit the use of motorized vehicles within the Blue-Grass BMU area to a specified percentage of the land. By limiting high levels of human activity in the area, effective habitat can be created for grizzly bears. The ROD and accompanying biological opinion from the U.S. Fish and Wildlife Service require the standards in the Access Amendment to be met by 2019. Currently, the BMU is not meeting the motorized access standards set forth in the Access Amendment.

The status of all roads in the BMU area is of great interest to CBP since the entire Blue-Grass BMU is within 10 miles of the Northern Border. CBP needs good access to this area to execute its mission to protect the Northern Border. Because there are limited options regarding which roads to close for motorized use that meet the Access Amendment standards and the ESA, and which provide border access to CBP, the Agencies are working together to determine acceptable alternatives.

Purpose and Need for Action

The purpose and need of the proposed action is to provide improved east-west access across the Selkirk Mountains on National Forest System lands that would: (1) Enable CBP to execute its statutory mission to protect the U.S. Northern Border and provide for the safety of CBP and other law enforcement officers in carrying out their duties and (2) meet Access Amendment standards for motorized access in a grizzly bear habitat in the Blue-Grass BMU area.

Proposed Action

Repairs and Maintenance to Bog Creek Road

One aspect of the proposed action would involve the repair and maintenance of an approximately 5.6-mile section of the existing Bog Creek Road between Forest Road (FR) 1013 and FR 2450 within the Blue-Grass BMU of the SRZ of the IPNF. The road is located in the Selkirk Mountains in Boundary County, Idaho, within approximately two miles of the Canadian border.

The Agencies anticipate that the proposed action would likely involve replacing or repairing damaged culverts, grading and resurfacing areas that have been heavily eroded by surface water flows, infilling potholes, and removing protruding boulders. Although widening Bog Creek Road is not a part of the proposed action, there may be areas which no longer meet minimum width requirements and may require cut and fill work to achieve the desired road operating and safety standards. Trees and other vegetation within the roadway and to either side would likely be grubbed or cut back to facilitate safe vehicle passage.

The proposed action would also likely include gathering and transporting fill materials (riprap, mixed soil/rock, and crushed aggregate) from "borrow" pits to use in general resurfacing/fill and in installation of the culvert replacements. Some equipment would be needed to perform the repairs and maintenance, including a dozer, a grader, a hydraulic excavator, and a dump truck. In addition, several pickup trucks or SUVs would be needed to transport construction personnel to and from the area. The Agencies anticipate that upon completion of the proposed repairs and maintenance, the 5.6-mile section of Bog Creek Road would remain closed for public motorized use and would be limited to administrative use only.

Closing Additional Roads for Motorized Use

Another aspect of the proposed action would involve the closure of certain roads within the Blue-Grass BMU. Bog Creek Road is located in the Blue-Grass BMU within the SRZ. This BMU area is currently not meeting Access Amendment standards for motorized access in a grizzly bear habitat. The Agencies anticipate that other roads within the Blue-Grass BMU area would need to be closed for motorized use under this proposed action. The road closures would be necessary to mitigate the potential impacts to grizzly bear habitats associated with the repair and subsequent use of Bog Creek Road and to allow the Forest Service to meet the Access Amendment standards and its statutory obligations under the ESA. Because there are limited options regarding roads to close for motorized use to meet the Access Amendment standards, the Agencies are working together to determine alternatives that would meet CBP's requirements for border access as well as the Forest Service's requirements to comply with the Access Amendment standards and the ESA.

The Agencies have identified a preliminary list of roads that could be closed for motorized use. All of these roads are currently closed to public use and only open for limited administrative use. Roads that have been preliminarily identified for possible motorized closure include FR 2464 Upper, 2464 Lower, 1322, 1322A, 1013D, 1013C, 1388, 1388A, 2252, 636, and 2253. Approximately 26 miles of IPNF roads could be closed under the proposed action. As a part of the scoping process (discussed below), the Agencies are seeking further input on possible motorized road closure alternatives.

Lead and Cooperating Agencies

CBP and the Forest Service will work together as joint lead agencies on the EIS.

Responsible Official

The Executive Director, Facilities Management & Engineering, CBP, is the deciding official for CBP and the Forest Supervisor, IPNF, Forest Service, is the deciding official for the Forest Service.

Public Scoping Process

Public scoping for the Bog Creek Road repair and maintenance proposal was initially conducted by CBP in February and March of 2013. Information gathered from the previous scoping effort was used to inform the Agencies about what level of NEPA analysis was necessary to evaluate the proposed project. The initial scoping information included the possibility that road closures may become part of the proposed action, but did not include specific motorized road closure information. Using initial scoping information, the Agencies determined that the NEPA analysis would be conducted through an EIS process. All scoping comments submitted during the initial scoping will be included in issue development for the current EIS process. A Scoping Report that summarizes the initial scoping effort is available for review at *http://www.cbp.gov/about/environmental-cultural-stewardship/nepa-documents/docs-review.*

This Notice of Intent (NOI) initiates the public scoping process which will guide the development of the EIS. All interested parties are invited to participate in the scoping process. CBP and the Forest Service invite agencies, organizations, and the general public to provide input to this process of scoping environmental issues for consideration in the EIS. Written comments may be submitted as described in the **ADDRESSES** section of this document. When submitting comments, please include your name and address. Comments received in response to this solicitation, including names and addresses of those who comment, will be part of the public record for this proposed action. Comments submitted anonymously will also be accepted and considered.

After the public scoping period is complete and the Agencies have reviewed the results, a compilation list of comments will be included in an amendment to the initial Scoping Report (described above). The amended Scoping Report will be made available on the CBP public Web site: *http://www.cbp.gov/about/environmental-cultural-stewardship/nepa-documents/docs-review.*

Public Involvement in Historic Preservation Activities Under Section 106 of the National Historic Preservation Act

Section 106 of the National Historic Preservation Act (54 U.S.C. 306108) requires Federal agencies to review all actions which may affect resources listed on, or eligible for, the National Register of Historic Places in order to take into account the effects of their undertakings on historic properties, and to afford the Idaho State Historic Preservation Officer and tribal governments a reasonable opportunity to comment on such undertakings. During the process of public scoping and preparation of the EIS, the Agencies seek to identify interested parties and obtain public comments on historic preservation issues related to the road repair and closure of roads for motorized use.

Preliminary Issues

Based upon the initial project scoping, some preliminary issues have been identified as potential effects of the proposed project. These include effects on:

- Border security;
- threatened and endangered species including grizzly bear, caribou, lynx, and bull trout;
- Blue-Grass BMU grizzly bear core habitat requirement;
- National Forest access; and
- biological resources including fisheries, wildlife, sensitive plants, and noxious weeds.

Permits and Licenses Required

The proposed project would likely require a Clean Water Act Section 404 Permit. The Agencies will work with the Idaho Department of Environmental Quality and the U.S. Army Corps of Engineers to determine the necessary permit process. All required permits would be obtained prior to project implementation.

Next Steps

In accordance with NEPA, the draft EIS will be made available to the public for review and comment through a Notice of Availability (NOA) in the **Federal Register**. The NOA will provide directions for obtaining copies of the draft EIS as well as dates and locations for any associated public participation meetings. After a public comment period on the draft EIS, CBP and the Forest Service will complete a final EIS.

Dated: April 21, 2016.

Karl H. Calvo,

Executive Director, Facilities Management and Engineering, Office of Administration.

Shanda Fallau Dekome,

Acting Forest Supervisor, Idaho Panhandle National Forests, U.S. Forest Service.

[FR Doc. 2016–09790 Filed 4–26–16; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0002; Internal Agency Docket No. FEMA–B–1610]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before July 26, 2016.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–1610, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *http://floodsrp.org/pdfs/srp_fact_sheet.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: April 12, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

I. Watershed-based studies:

Community	Community map repository address
Upper Sangamon River Watershed	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Macon County, Illinois, and Incorporated Areas	
City of Decatur	City Hall, 1 Gary K. Anderson Plaza, Decatur, IL 62523.
Unincorporated Areas of Macon County	Macon County Office Building, 141 South Main Street Decatur, IL 62523.
Village of Forsyth	Village Hall, 301 South Route 51, Forsyth, IL 62535.

II. Non-watershed-based studies:

Community	Community map repository address
Mendocino County, California and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 15–09–0493S Preliminary Date: August 28, 2015	
City of Willits	City Planning Department, 111 East Commercial Street, Willits, CA 95490.
Unincorporated Areas of Mendocino County	Planning Department, 860 North Bush Street, Ukiah, CA 95482.
Mendocino County, California and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 11–09–0848S Preliminary Date: September 14, 2015	
City of Fort Bragg	Community Development Department, 416 North Franklin Street, Fort Bragg, CA 95437.
City of Point Arena	City Hall, 451 School Street, Point Arena, CA 95468.
Unincorporated Areas of Mendocino County	Planning Department, 860 North Bush Street, Ukiah, CA 95482.
Placer County, California and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 11–09–0868S Preliminary Date: December 28, 2015	
City of Auburn	Planning and Public Works Department, 1225 Lincoln Way, Auburn, CA 95603.
City of Lincoln	Engineering Department, 600 Sixth Street, Lincoln, CA 95648.
City of Rocklin	Engineering Department, 3970 Rocklin Road, Rocklin, CA 95677.
City of Roseville	Engineering Department, 311 Vernon Street, Roseville, CA 95678.
Town of Loomis	Town Hall, 3665 Taylor Road, Loomis, CA 95650.
Unincorporated Areas of Placer County	Placer County Public Works and Facilities, 3091 County Center Drive, Auburn, CA 95603.
Gladwin County, Michigan (All Jurisdictions)	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project:12–05–2231S Preliminary Date: March 27, 2015	
City of Beaverton	124 West Brown Street, Beaverton, MI 48612.
City of Gladwin	1000 West Cedar Avenue, Gladwin, MI 48624.
Township of Beaverton	4496 Dale Road, Beaverton, MI 48612.
Township of Billings	1050 Estey Road, Beaverton, MI 48612.
Township of Bourret	2749 School Road, Alger, MI 48610.
Township of Buckeye	1498 South Hockaday Road, Beaverton, MI 48624.
Township of Butman	5005 North Hockaday Road, Gladwin, MI 48624.
Township of Clement	1497 E M–30, Alger, MI 48610.
Township of Gladwin	2001 Wagarville Road, Gladwin, MI 48624.
Township of Grout	1490 South Grout Road, Gladwin, MI 48624.
Township of Hay	1220 East Highwood Road, Beaverton, MI 48612.
Township of Sage	1831 North Pratt Lake Road, Gladwin, MI 48624.
Township of Secord	1507 Secord Dam Road, Gladwin, MI 48624.
Township of Sherman	4013 Oberlin Road, Gladwin, MI 48624.
Township of Tobacco	1826 Dale Road, Beaverton, MI 48612.

Community	Community map repository address
Houston County, MN and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project:11–05–1551S Preliminary Dates: December 31, 2014 & January 15, 2016	
City of Brownsville	City Hall, 104 North 6th Street, Brownsville, MN 55919.
City of Caledonia	City Hall, 231 East Main Street, Caledonia, MN 55921.
City of Hokah	City Hall, 102 Main Street, Hokah, MN 55941.
City of Houston	City Hall, 105 West Maple Street, Houston, MN 55943.
City of La Crescent	City Hall, 315 Main Street, La Crescent, MN 55947.
City of Spring Grove	City Hall, 118 First Avenue Northwest, Spring Grove, MN 55974.
Township of La Crescent	Township Hall, 830 Town Hall Road, La Crescent, MN 55947.
Unincorporated Areas of Houston County	Houston County Courthouse, 304 South Marshall Street, Caledonia, MN 55921.
Fairfield County, Ohio and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project:14–05–9584S Preliminary Date: January 4, 2016	
City of Lancaster	City Building Department, 121 East Chestnut Street, Lancaster, OH 43130.
City of Pickerington	City Hall, 51 East Columbus Street, Pickerington, OH 43147.
Unincorporated Areas of Fairfield County	Fairfield County Administrative Courthouse, 210 East Main Street, Lancaster, OH 43130.

[FR Doc. 2016–09820 Filed 4–26–16; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2016–0004; OMB No. 1660–0098]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Citizen Corps Council Registration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission will describe the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort and resources used by respondents to respond) and cost, and the actual data collection instruments FEMA will use.

DATES: Comments must be submitted on or before May 27, 2016.

ADDRESSES: Submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the Desk Officer for the Department of Homeland Security, Federal Emergency Management Agency, and sent via electronic mail to *oira.submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Records Management Division, 500 C Street SW., Washington, DC 20472–3100, or email address *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: This information collection previously published in the **Federal Register** on February 10, 2016, at 81 FR 7137 with a 60 day public comment period. No comments were received. The purpose of this notice is to notify the public that FEMA will submit the information collection abstracted below to the Office of Management and Budget for review and clearance.

Collection of Information

Title: Citizen Corps Council Registration.

Type of Information Collection: Revision of a currently approved information collection.

OMB Number: 1660–0098.

Form Titles and Numbers: FEMA Form 008–0–25, Citizen Corps Council Registration.

Abstract: FEMA's Community Preparedness Division would like to revise a currently approved collection for its registration of State, local, Tribal and territorial Councils and Community Emergency Response Teams (CERT). The registration process allows for new Councils to submit information on the Council or CERT to the State Citizen Corps Program Manager for approval. The revised registration process will allow for the collection of more valuable information and the tool is more user-friendly for Citizen Corps Councils and CERTs.

Affected Public: State, local or Tribal Government.

Estimated Number of Respondents: 3,900.

Estimated Total Annual Burden Hours: 3,900 hours.

Estimated Cost: The estimated annual cost to respondents for the hour burden is $93,249.00. There are no annual costs to respondents operations and maintenance costs for technical services. There is no annual start-up or capital costs. The cost to the Federal Government is $378,690.00.

Dated: April 20, 2016.

Richard W. Mattison,

Records Management Program Chief, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2016–09843 Filed 4–26–16; 8:45 am]

BILLING CODE 9110–21–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0002; Internal Agency Docket No. FEMA–B–1618]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Title 44, part 65 of the Code of Federal Regulations (44 CFR part 65). The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will become effective on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: April 12, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Effective date of modification	Community No.
Alabama: Coffee	City of Enterprise (15–04–A168P).	The Honorable Kenneth W. Boswell, Mayor, City of Enterprise, P.O. Box 311000, Enterprise, AL 36330.	City Hall, 501 South Main Street, Enterprise, AL 36331.	*http://www.msc.fema.gov/lomc.*	Jul. 11, 2016	010045
Arkansas: Benton.	Unincorporated areas of Benton County (15–06–4245P).	The Honorable Robert D. Clinard, Benton County Judge, 215 East Central Avenue, Bentonville, AR 72712.	Benton County, Planning Department, 905 Northwest 8th Street, Bentonville, AR 72712.	*http://www.msc.fema.gov/lomc.*	Jul. 20, 2016	050419
Colorado:						
Boulder	City of Boulder (15–08–0360P).	The Honorable Suzanne Jones, Mayor, City of Boulder, P.O. Box 791, Boulder, CO 80306.	Planning and Development Services Department, 1739 Broadway Street, Boulder, CO 80302.	*http://www.msc.fema.gov/lomc.*	Jul. 22, 2016	080024

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Effective date of modification	Community No.
Jefferson	Unincorporated areas of Jefferson County (15–08–0540P).	The Honorable Casey Tighe, Chairman, Jefferson County Board of Commissioners, 100 Jefferson County Parkway, Golden, CO 80419.	Jefferson County Department of Planning and Zoning, 100 Jefferson County Parkway, Golden, CO 80419.	*http://www.msc.fema.gov/lomc.*	Jul. 22, 2016	080087
Weld	City of Greeley (15–08–0573P).	The Honorable Tom Norton, Mayor, City of Greeley, 1000 10th Street, Greeley, CO 80631.	City Hall, 1000 10th Street, Greeley, CO 80631.	*http://www.msc.fema.gov/lomc.*	Jul. 14, 2016	080184
Weld	Unincorporated areas of Weld County (15–08–0573P).	The Honorable Mike Freeman, Chairman, Weld County Board of Commissioners, P.O. Box 758, Greeley, CO 80632.	Weld County Planning and Zoning Department, 1555 North 17th Avenue, Greeley, CO 80631.	*http://www.msc.fema.gov/lomc.*	Jul. 14, 2016	080266
District of Columbia.	District of Columbia (16–03–0242P).	The Honorable Muriel Bowser, Mayor, District of Columbia, 1350 Pennsylvania Avenue Northwest, Washington, DC 20004.	Department of Energy and Environment, 1200 1st Street Northeast, 5th Floor, Washington, DC 20002.	*http://www.msc.fema.gov/lomc.*	Jul. 28, 2016	110001
Florida:						
Broward	City of Fort Lauderdale (15–04–7586P).	The Honorable John P. Seiler, Mayor, City of Fort Lauderdale, 100 North Andrews Avenue, 8th Floor, Fort Lauderdale, FL 33301.	Building Services Department, 700 Northwest 19th Avenue, Plantation, FL 33311.	*http://www.msc.fema.gov/lomc.*	Jul. 14, 2016	125105
Broward	Unincorporated areas of Broward County (15–04–7586P).	Ms. Bertha Henry, Broward County Administrator, 115 South Andrews Avenue, Fort Lauderdale, FL 33301.	Broward County Environmental Licensing and Building Permitting Division, 1 North University Drive, Fort Lauderdale, FL 33311.	*http://www.msc.fema.gov/lomc.*	Jul. 14, 2016	125093
Indian River	City of Vero Beach (16–04–2464P).	The Honorable Jay Kramer, Mayor, City of Vero Beach, 1053 20th Place, Vero Beach, FL 32960.	City Hall, 1053 20th Place, Vero Beach, FL 32960.	*http://www.msc.fema.gov/lomc.*	Jul. 26, 2016	120124
Lake	Unincorporated areas of Lake County (15–04–2425P).	The Honorable Sean Parks, Chairman, Lake County Board of Commissioners, P.O. Box 7800, Tavares, FL 32778.	Lake County Public Works Department, 323 North Sinclair Avenue, Tavares, FL 32778.	*http://www.msc.fema.gov/lomc.*	Jul. 25, 2016	120421
Miami-Dade	City of Miami (16–04–1012P).	The Honorable Tomás P. Regalado, Mayor, City of Miami, 3500 Pan American Drive, Miami, FL 33133.	Emergency Management Department, 444 Southwest 2nd Avenue, 10th Floor, Miami, FL 33130.	*http://www.msc.fema.gov/lomc.*	Jul. 29, 2016	120650
Osceola	City of Kissimmee (14–04–A515P).	The Honorable Jim Swan, Mayor, City of Kissimmee, 101 Church Street, Kissimmee, FL 34741.	Engineering Department, 101 Church Street, Kissimmee, FL 34741.	*http://www.msc.fema.gov/lomc.*	Jul. 27, 2016	120190
Osceola	Unincorporated areas of Osceola County (14–04–A515P).	The Honorable Viviana Janer, Chair, Osceola County Board of Commissioners, 1 Courthouse Square, Suite 4700, Kissimmee, FL 34741.	Osceola County Stormwater Department, 1 Courthouse Square, Suite 3100, Kissimmee, FL 34741.	*http://www.msc.fema.gov/lomc.*	Jul. 27, 2016	120189
St. Lucie	City of Fort Pierce (16–04–2206P).	The Honorable Linda Hudson, Mayor, City of Fort Pierce, 100 North U.S. Highway 1, Fort Pierce, FL 34950.	Building Department, 100 North U.S., Highway 1, Fort Pierce, FL 34950.	*http://www.msc.fema.gov/lomc.*	Jul. 26, 2016	120286
St. Lucie	Unincorporated areas of St. Lucie County (16–04–2206P).	The Honorable Kim Johnson, Chairman, St. Lucie County Board of Commissioners, 2300 Virginia Avenue, Fort Pierce, FL 34982.	St. Lucie County Planning and Development Department, 2300 Virginia Avenue, Fort Pierce, FL 34982.	*http://www.msc.fema.gov/lomc.*	Jul. 26, 2016	120285
Georgia: Chatham.	City of Pooler (16–04–1717P).	The Honorable Mike Lamb, Mayor, City of Pooler, 100 Southwest Highway 80, Pooler, GA 31322.	Zoning Administration Division, 100 Southwest, Highway 80, Pooler, GA 31322.	*http://www.msc.fema.gov/lomc.*	Jul. 13, 2016	130261
Kentucky:						
Hardin	City of Elizabethtown (15–04–9058P).	The Honorable Edna Berger, Mayor, City of Elizabethtown, P.O. Box 550, Elizabethtown, KY 42702.	City Hall, 200 West Dixie Avenue, Elizabethtown, KY 42701.	*http://www.msc.fema.gov/lomc.*	Jul. 19, 2016	210095
Hardin	Unincorporated areas of Hardin County (15–04–9058P).	The Honorable Harry L. Berry, Hardin County Judge/Executive, P.O. Box 568, Elizabethtown, KY 42702.	Hardin County Planning and Development Commission, 150 North Provident Way, Suite 225, Elizabethtown, KY 42701.	*http://www.msc.fema.gov/lomc.*	Jul. 19, 2016	210094

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Effective date of modification	Community No.
Louisiana: East Baton Rouge.	City of Central (15–06–4438P).	The Honorable Jr. Shelton, Mayor, City of Central, 13421 Hooper Road, Suite 9, Central, LA 70818.	Planning and Zoning Commission, 6703 Sullivan Road, Central, LA 70739.	*http://www.msc.fema.gov/lomc.*	Jul. 15, 2016	220060
Maine: Hancock	Town of Gouldsboro (15–01–2374P).	The Honorable Dana Rice, Chair, Town of Gouldsboro Board of Selectmen, P.O. Box 68, Prospect Harbor, ME 04669.	Town Hall, 59 Main Street, Prospect Harbor, ME 04669.	*http://www.msc.fema.gov/lomc.*	Jun. 24. 2016	230283
Maryland: Cecil	Town of Port Deposit (15–03–2779P).	The Honorable Wayne L. Tome, Sr., Mayor, Town of Port Deposit, 64 South Main Street, Port Deposit, MD 21904.	Town Hall, 64 South Main Street, Port Deposit, MD 21904.	*http://www.msc.fema.gov/lomc.*	Aug, 1, 2016	240025
Cecil	Unincorporated areas of Cecil County (15–03–2779P).	The Honorable Tari Moore, Cecil County Executive, 200 Chesapeake Boulevard, Suite 2100, Elkton, MD 21921.	Cecil County Department of Planning and Zoning, 200 Chesapeake Boulevard, Suite 2300, Elkton, MD 21921.	*http://www.msc.fema.gov/lomc.*	Aug, 1, 2016	240019
Harford	Unincorporated areas of Harford County (15–03–2779P).	The Honorable Barry Glassman, Harford County Executive, 220 South Main Street, Bel Air, MD 21014.	Harford County Department of Planning and Zoning, 220 South Main Street, Bel Air, MD 21014.	*http://www.msc.fema.gov/lomc.*	Aug, 1, 2016	240040
Massachusetts: Barnstable	Town of Chatham (16–01–0500P).	The Honorable Jeffrey S. Dykens, Chairman, Town of Chatham Board of Selectmen, 549 Main Street, Chatham, MA 02633.	Community Development Department, 261 George Ryder Road, Chatham, MA 02633.	*http://www.msc.fema.gov/lomc.*	Jul. 8, 2016	250004
Barnstable	Town of Harwich (16–01–0500P).	The Honorable Peter S. Hughes, Chairman, Town of Harwich Board of Selectmen, 732 Main Street, Harwich, MA 02645.	Town Hall, 732 Main Street, Harwich, MA 02645.	*http://www.msc.fema.gov/lomc.*	Jul. 8, 2016	250008
Mississippi: Copiah	City of Hazlehurst (15–04–7795P).	The Honorable Henry Banks, Mayor, City of Hazlehurst, 209 South Extension Street, Hazlehurst, MS 39083.	City Hall, 209 South Extension Street, Hazlehurst, MS 39083.	*http://www.msc.fema.gov/lomc.*	Jul. 28, 2016	280046
Copiah	Unincorporated areas of Copiah County (15–04–7795P).	The Honorable Perry L. Hood, President, Copiah County Board of Supervisors, P.O. Box 551, Hazlehurst, MS 39083.	Copiah County Circuit Clerk's Office, 100 Caldwell Street, Hazlehurst, MS 39083.	*http://www.msc.fema.gov/lomc.*	Jul. 28, 2016	280221
Montana: Ravalli	Unincorporated areas of Ravalli County (16–08–0080P).	The Honorable Ray Hawk, Chairman, Ravalli County Board of Commissioners, 215 South 4th Street, Suite A, Hamilton, MT 59840.	Ravalli County Planning Department, 215 South 4th Street, Suite F, Hamilton, MT 59840.	*http://www.msc.fema.gov/lomc.*	Jul. 28, 2016	300061
New Hampshire: Rockingham.	Town of Windham (15–01–1350P).	The Honorable Joel Desilets, Chairman, Town of Windham Board of Selectmen, 3 North Lowell Road, Windham, NH 03087.	Community Development Department, 3 North Lowell Road, Windham, NH 03087.	*http://www.msc.fema.gov/lomc.*	Jul. 14, 2016	330144
New Mexico: Bernalillo.	Unincorporated areas of Bernalillo County (15–06–4028P).	The Honorable Art De La Cruz, Chairman, Bernalillo County Board of Commissioners, 1 Civic Plaza Northwest, Albuquerque, NM 87102.	Bernalillo County Public Works Department, 2400 Broadway Southeast, Albuquerque, NM 87102.	*http://www.msc.fema.gov/lomc.*	Jun 7, 2016	350001
Oklahoma: Tulsa.	City of Tulsa (15–06–0681P).	The Honorable Dewey Bartlett, Jr., Mayor, City of Tulsa, 175 East 2nd Street, 15th Floor, Tulsa, OK 74103.	Stormwater Design Department, 2317 South Jackson Avenue, Suite 302, Tulsa, OK 74103.	*http://www.msc.fema.gov/lomc.*	Jul. 19, 2016	405381
Pennsylvania: Delaware	Borough of Trainer (15–03–2447P).	The Honorable Frances Zalewski, Mayor, Borough of Trainer, 824 Main Street, Trainer, PA 19061.	Borough Hall, 824 Main Street, Trainer, PA 19061.	*http://www.msc.fema.gov/lomc.*	Jul. 13, 2016	420437
Elk	Borough of Johnsonburg (14–03–2810P).	The Honorable Theresa Cherry, Mayor, Borough of Johnsonburg, 100 Main Street, Johnsonburg, PA 15845.	Borough Hall, 100 Main Street, Johnsonburg, PA 15845.	*http://www.msc.fema.gov/lomc.*	Jun. 27, 2016	420443
Elk	Township of Ridgway (14–03–2810P).	The Honorable Richard Glover, Chairman, Township of Ridgway Board of Supervisors, 1537–A Montmorenci Road, Ridgway, PA 15853.	Township Municipal Building, 1537–A Montmorenci Road, Ridgway, PA 15853.	*http://www.msc.fema.gov/lomc.*	Jun. 27, 2016	420445

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Effective date of modification	Community No.
Tennessee: Hamblen.	City of Morristown (15–04–7679P).	The Honorable Gary Chesney, Mayor, City of Morristown, 100 West 1st North Street, Morristown, TN 37814.	Community Development and Planning Department, 100 West 1st North Street, Morristown, TN 37814.	*http://www.msc.fema.gov/lomc.*	Jul. 7, 2016	470070
Texas:						
Bexar	City of San Antonio (16–06–0036P).	The Honorable Ivy R. Taylor, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, TX 78283.	Transportation and Capital Improvements Department, Storm Water Division, 1901 South Alamo Street, 2nd Floor, San Antonio, TX 78204.	*http://www.msc.fema.gov/lomc.*	Jul. 11, 2016	480045
Bexar	City of San Antonio (16–06–0941P).	The Honorable Ivy R. Taylor, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, TX 78283.	Transportation and Capital Improvements Department, Storm Water Division, 1901 South Alamo Street, 2nd Floor, San Antonio, TX 78204.	*http://www.msc.fema.gov/lomc.*	Jul. 15, 2016	480045
Collin	City of Frisco (15–06–3867P).	The Honorable Maher Maso, Mayor, City of Frisco, 6101 Frisco Square Boulevard, Frisco, TX 75034.	Engineering Services Department, 6101 Frisco Square Boulevard, 3rd Floor, Frisco, TX 75034.	*http://www.msc.fema.gov/lomc.*	Jul. 11, 2016	480134
Collin	City of McKinney (15–06–3643P).	The Honorable Brian Loughmiller, Mayor, City of McKinney, P.O. Box 517, McKinney, TX 75070.	Engineering Department, 221 North Tennessee Street, McKinney, TX 75069.	*http://www.msc.fema.gov/lomc.*	Jul. 11, 2016	480135
Collin	City of McKinney (16–06–0893P).	The Honorable Brian Loughmiller, Mayor, City of McKinney, P.O. Box 517, McKinney, TX 75070.	Engineering Department, 221 North Tennessee Street, McKinney, TX 75069.	*http://www.msc.fema.gov/lomc.*	Jul. 11, 2016	480135
Denton	City of Fort Worth (15–06–1721P).	The Honorable Betsy Price, Mayor, City of Fort Worth, 1000 Throckmorton Street, Fort Worth, TX 76102.	Stormwater Management Division, 1000 Throckmorton Street, Fort Worth, TX 76102.	*http://www.msc.fema.gov/lomc.*	Jul. 1, 2016	480596
Denton	Town of Northlake (15–06–1721P).	The Honorable Peter Dewing, Mayor, Town of Northlake, 1400 FM 407, Northlake, TX 76247.	Public Works Department, 1400 FM 407, Northlake, TX 76247.	*http://www.msc.fema.gov/lomc.*	Jul. 1, 2016	480782
Denton	Unincorporated areas of Denton County (15–06–1721P).	The Honorable Mary Horn, Denton County Judge, 110 West Hickory Street, 2nd Floor, Denton, TX 76201.	Denton County, Public Works Department, Engineering Division, 1505 East McKinney Street, Suite 175, Denton, TX 76209.	*http://www.msc.fema.gov/lomc.*	Jul. 1, 2016	480774
Lamar	City of Paris (14–06–4102P).	The Honorable AJ Hashmi, Mayor, City of Paris, 135 Southeast 1st Street, Paris, TX 75460.	Engineering, Planning and Development Department, 135 Southeast 1st Street, Paris, TX 75460.	*http://www.msc.fema.gov/lomc.*	Jul. 11, 2016	480427
Midland	City of Midland (15–06–4466P).	The Honorable Jerry Morales, Mayor, City of Midland, 300 North Loraine Street, Midland, TX 79701.	Engineering Department, 300 North Loraine Street, Midland, TX 79701.	*http://www.msc.fema.gov/lomc.*	Jul. 20, 2016	480477
Montgomery	Unincorporated areas of Montgomery County (16–06–0123P).	The Honorable Craig Doyal, Montgomery County Judge, 501 North Thompson, Suite 401, Conroe, TX 77301.	Montgomery County Engineering Department, 501 North Thompson Street, Suite 103, Conroe, TX 77301.	*http://www.msc.fema.gov/lomc.*	Jul. 14, 2016	480483
Parker	City of Weatherford (15–06–1755P).	The Honorable Dennis Hooks, Mayor, City of Weatherford, P.O. Box 255, Weatherford, TX 76086.	Department of Code Enforcement, 303 Palo Pinto Street, Weatherford, TX 76086.	*http://www.msc.fema.gov/lomc.*	Jul. 20, 2016	480522
Travis	City of Austin (15–06–3816P).	The Honorable Steve Adler, Mayor, City of Austin, P.O. Box 1088, Austin, TX 78767.	Watershed Engineering Division, 505 Barton Springs Road, 12th Floor, Austin, TX 78767.	*http://www.msc.fema.gov/lomc.*	Jul. 5, 2016	480624
Williamson	Unincorporated areas of Williamson County (15–06–4383P).	The Honorable Dan A. Gattis, Williamson County Judge, 710 South Main Street, Suite 101, Georgetown, TX 78626.	Williamson County Department of Infrastructure, 3151 Southeast Inner Loop, Suite B, Georgetown, TX 78626.	*http://www.msc.fema.gov/lomc.*	Jul. 7, 2016	481079
Utah:						

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Effective date of modification	Community No.
Utah	City of Alpine (16–08–0236P).	The Honorable Sheldon Wimmer, Mayor, City of Alpine, 20 North Main, Alpine, UT 84004.	Public Works Department, 181 East 200 North, Alpine, UT 84004.	*http://www.msc.fema.gov/lomc.*	Sep. 2, 2016	490228
Utah	City of Spanish Fork (15–08–0248P).	The Honorable Steve Leifson, Mayor, City of Spanish Fork, 40 South Main Street, Spanish Fork, UT 84660.	Engineering Department, 40 South Main Street, Spanish Fork, UT 84660.	*http://www.msc.fema.gov/lomc.*	Jul. 8, 2016	490241
Utah	Unincorporated areas of Utah County (15–08–0248P).	The Honorable Larry Ellertson, Chairman, Utah County Board of Commissioners, 100 East Center Street, Suite 2300, Provo, UT 84606.	Utah County Community Development Department, 51 South University Avenue, Suite 117, Provo, UT 84601.	*http://www.msc.fema.gov/lomc.*	Jul. 8, 2016	495517
Virginia: Prince William.	Unincorporated areas of Prince William County (16–03–0467P).	The Honorable Corey A. Stewart, Chairman At-Large, Prince William County, Board of Supervisors, 1 County Complex Court, Prince William, VA 22192.	Prince William County Department of Public Works, 5 County Complex Court, Prince William, VA 22192.	*http://www.msc.fema.gov/lomc.*	Jun. 30, 2016	510119

[FR Doc. 2016–09821 Filed 4–26–16; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0002]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below.

The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

DATES: The effective date of September 16, 2016 which has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *www.msc.fema.gov* by the effective date indicated above.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov.* The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: April 12, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Prince George's County, Maryland, and Incorporated Areas	
Docket No.: FEMA–B–1510	
City of Laurel	Municipal Center, 8103 Sandy Spring Road, Laurel, MD 20707.
Unincorporated Areas of Prince George's County	Prince George's County Department of the Environment, 1801 McCormick Drive, Suite 500, Largo, MD 20774.

Community	Community map repository address
Northumberland County, Pennsylvania (All Jurisdictions)	
Docket No.: FEMA–B–1530	
City of Sunbury	City Hall, 225 Market Street, Sunbury, PA 17801.
Township of Upper Augusta	Upper Augusta Township Municipal Building, 2087 Snydertown Road, Sunbury, PA 17801.

[FR Doc. 2016–09848 Filed 4–26–16; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2015–0024; OMB No. 1660–0100]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; General Admissions Applications (Long and Short) and Stipend Forms

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission will describe the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort and resources used by respondents to respond) and cost, and the actual data collection instruments FEMA will use.

DATES: Comments must be submitted on or before May 27, 2016.

ADDRESSES: Submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the Desk Officer for the Department of Homeland Security, Federal Emergency Management Agency, and sent via electronic mail to *oira.submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Records Management Division, 500 C Street SW., Washington, DC 20472–3100, or email address *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection previously published in the **Federal Register** on January 26, 2016 at 81 FR 4330 with a 60 day public comment period. No comments were received. The purpose of this notice is to notify the public that FEMA will submit the information collection abstracted below to the Office of Management and Budget for review and clearance.

Collection of Information

Title: General Admissions Applications (Long and Short) and Stipend Forms.

Type of Information Collection: Revision of a currently approved information collection.

OMB Number: 1660–0100.

Form Titles and Numbers: The form numbers have changed in accordance with the Federal Enterprise Architecture (FEA) numbering system. FEMA Form 119–25–0–1, General Admissions Application; FEMA Form 119–25–0–3, Student Stipend Agreement; FEMA Form 119–25–0–4, Student Stipend Agreement (Amendment); FEMA Form 119–25–0–5, National Fire Academy Executive Fire Officer Program Application for Admission; and FEMA Form 119–25–0–6, Training Registration Form.

Abstract: FEMA provides training to advance the professional development of personnel engaged in fire prevention and control and emergency managemernt activities through its Center for Domestic Preparedness, Emergency Management Institute, National Fire Academy, National Training and Education Division, National Domestic Preparedness Consortium, and Rural Domestic Preparedness Consortium. FEMA Form 119–25–0–1 has an increase in the number of respondents from 25,000 to 52,000 (+27,000) because FEMA is replacing all existing General Admissions Application and Training Registration forms with a single FEMA-wide form which will be submitted as a paper version or using an on-line application process. There was also an adjustment increase for FEMA Form 119–25–0–1 from 3,750 hours to 7,800 (+4,050) hours. The FEMA Form 119–25–0–6 has been created for those courses where less information is required from the respondent. It is expected that 154,500 respondents will used this form requiring 15,450 burden hours. The FEMA Form 119–25–2 (reduction of 80,000 respondents and 8,000 burden hours) is being eliminated and being replaced by the FEMA Form 119–25–0–1.

Affected Public: State, Local or Tribal Government, Business or other for-profit, Not-for-profit institutions and Federal Government.

Estimated Number of Respondents: 214,300.

Estimated Total Annual Burden Hours: 24,400.

Estimated Cost: 2,063,978.

Dated: April 20, 2016.

Richard W. Mattison,

Records Management Program Chief, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2016–09844 Filed 4–26–16; 8:45 am]

BILLING CODE 9111–72–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final notice.

SUMMARY: New or modified Base (1-percent annual chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or regulatory floodways (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance

Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports, currently in effect for the listed communities. The flood hazard determinations modified by each LOMR will be used to calculate flood insurance premium rates for new buildings and their contents.

DATES: The effective date for each LOMR is indicated in the table below.

ADDRESSES: Each LOMR is available for inspection at both the respective Community Map Repository address listed in the table below and online through the FEMA Map Service Center at *www.msc.fema.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final flood hazard determinations as shown in the LOMRs for each community listed in the table below. Notice of these modified flood hazard determinations has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The new or modified flood hazard information is the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP).

This new or modified flood hazard information, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.

This new or modified flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings, and for the contents in those buildings. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov.*

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: April 11, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Effective date of modification	Community No.
Arizona:					
Maricopa (FEMA Docket No.: B–1556).	City of Buckeye (15–09–0476P).	The Honorable Jackie A. Meck, Mayor, City of Buckeye, 530 East Monroe Avenue, Buckeye, AZ 85326.	Engineering Department, 530 East Monroe Avenue, Buckeye, AZ 85326.	Feb. 19, 2016	040039
Maricopa (FEMA Docket No.: B–1556).	City of Buckeye (15–09–1721P).	The Honorable Jackie A. Meck, Mayor, City of Buckeye, 530 East Monroe Avenue, Buckeye, AZ 85326.	Engineering Department, 530 East Monroe Avenue, Buckeye, AZ 85326.	Mar. 4, 2016	040039
Maricopa (FEMA Docket No.: B–1552).	Town of Queen Creek (15–09–0910P).	The Honorable Gail Barney, Mayor, Town of Queen Creek, 22350 South Ellsworth Road, Queen Creek, AZ 85142.	Town Hall, 22350 South Ellsworth Road, Queen Creek, AZ 85142.	Dec. 28, 2015	040132
Maricopa (FEMA Docket No.: B–1552).	City of Scottsdale (15–09–2058P).	The Honorable W.J. Jim Lane, Mayor, City of Scottsdale, 3939 North Drinkwater Boulevard, Scottsdale, AZ 85251.	City Hall, 3939 North Drinkwater Boulevard, Scottsdale, AZ 85251.	Jan. 8, 2016	045012
Maricopa (FEMA Docket No.: B–1552).	City of Tempe (15–09–2580P).	The Honorable Mark Mitchell, Mayor, City of Tempe, P.O. Box 5002, Tempe, AZ 85280.	Engineering Department City Hall, 31 East 5th Street, Tempe, AZ 85281.	Feb. 5, 2016	040054
Maricopa (FEMA Docket No.: B–1556).	Unincorporated areas of Maricopa County (15–09–0476P).	The Honorable Steve Chucri, Chairman, Board of Supervisors, Maricopa County, 301 West Jefferson Street, 10th Floor, Phoenix, AZ 85003.	Flood Control District of Maricopa County, 2801 West Durango Street, Phoenix, AZ 85009.	Feb. 19, 2016	040037
Maricopa (FEMA Docket No.: B–1552).	Unincorporated areas of Maricopa County (15–09–0910P).	The Honorable Steve Chucri, Chairman, Board of Supervisors, Maricopa County, 301 West Jefferson Street, 10th Floor, Phoenix, AZ 85003.	Flood Control District of Maricopa County, 2801 West Durango Street, Phoenix, AZ 85009.	Dec. 28, 2015	040037
Pima (FEMA Docket No.: B–1556).	Town of Marana (15–09–1240P).	The Honorable Ed Honea, Mayor, Town of Marana, 11555 West Civic Center Drive, Marana, AZ 85653.	Engineering Department, 11555 West Civic Center Drive, Marana, AZ 85653.	Feb. 11, 2016	040118
Pima (FEMA Docket No.: B–1552).	Unincorporated areas of Pima County (14–09–4178P).	The Honorable Sharon Bronson, Chair, Board of Supervisors, Pima County, 130 West Congress Street, 11th Floor, Tucson, AZ 85701.	Pima County Flood Control District, 210 North Stone Avenue, 9th Floor, Tucson, AZ 85701.	Jan. 25, 2016	040073
Pima (FEMA Docket No.: B–1556).	Unincorporated areas of Pima County (15–09–2370P).	The Honorable Sharon Bronson, Chair, Board of Supervisors, Pima County, 130 West Congress Street, 11th Floor, Tucson, AZ 85701.	Pima County Flood Control District, 210 North Stone Avenue 9th Floor, Tucson, AZ 85701.	Feb. 12, 2016	040073

State and county	Location and case No.	Chief executive officer of community	Community map repository	Effective date of modification	Community No.
Pinal (FEMA Docket No.: B–1552).	Unincorporated areas of Pinal County (15–09–0910P).	The Honorable Cheryl Chase, Chair, Board of Supervisors, Pinal County, 135 North Pinal Street, Florence, AZ 85132.	Engineering Department, 135 North Pinal Street, Building F, Florence, AZ 85132.	Dec. 28, 2015	040077
Pinal (FEMA Docket No.: B–1556).	Unincorporated areas of Pinal County (15–09–1991P).	The Honorable Cheryl Chase, Chair, Board of Supervisors, Pinal County, 135 North Pinal Street, Florence, AZ 85132.	Engineering Department, 31 North Pinal Street, Building F, Florence, AZ 85132.	Feb. 11, 2016	040077
Pinal (FEMA Docket No.: B–1556).	Unincorporated areas of Pinal County (15–09–2521P).	The Honorable Cheryl Chase, Chair, Board of Supervisors, Pinal County, 135 North Pinal Street, Florence, AZ 85132.	Engineering Department, 31 North Pinal Street, Building F, Florence, AZ 85132.	Mar. 2, 2016	040077
Yavapai (FEMA Docket No.: B–1552).	Town of Prescott Valley (15–09–1138P).	The Honorable Harvey C. Skoog, Mayor, Town of Prescott Valley, 7501 East Civic Circle, Prescott Valley, AZ 86314.	Engineering Division, 7501 East Civic Circle, Prescott Valley, AZ 86314.	Jan. 8, 2016	040121
California:					
Alameda (FEMA Docket No.: B–1556).	City of Dublin (15–09–1152P).	The Honorable David Haubert, Mayor, City of Dublin, 100 Civic Plaza, Dublin, CA 94568.	Public Works Department, 100 Civic Plaza, Dublin, CA 94568.	Mar. 8, 2016	060705
Riverside (FEMA Docket No.: B–1556).	City of Wildomar (15–09–2570P).	The Honorable Ben Benoit, Mayor, City of Wildomar, 23873 Clinton Keith Road, Suite 201, Wildomar, CA 92595.	City Hall, 23873 Clinton Keith Road, Suite 201, Wildomar, CA 92595.	Feb. 26, 2016	060221
Sacramento (FEMA Docket No.: B–1556).	Unincorporated areas of Sacramento County (15–09–2776P).	The Honorable Phil Serna, Chairman, Board of Supervisors, Sacramento County, 700 H Street, Suite 2450, Sacramento, CA 95814.	Municipal Services Agency, Department of Water Resources, 827 7th Street, Suite 301, Sacramento, CA 95814.	Feb. 17, 2016	060262
San Diego (FEMA Docket No.: B–1552).	City of Santee (14–09–3827P).	The Honorable Randy Voepel, Mayor, City of Santee, 10601 Magnolia Avenue, Santee, CA 92071.	City Hall, 10601 Magnolia Drive, Santee, CA 92071.	Jan. 29, 2016	060703
San Diego (FEMA Docket No.: B–1552).	Unincorporated areas of San Diego County (14–09–3827P).	The Honorable Bill Horn, Chairman, Board of Supervisors, San Diego County, 1600 Pacific Highway, San Diego, CA 92101.	Department of Public Works, Flood Control, 5201 Ruffin Road, Suite P, San Diego, CA 92123.	Jan. 29, 2016	060284
San Diego (FEMA Docket No.: B–1552).	Unincorporated areas of San Diego County (14–09–3829P).	The Honorable Bill Horn, Chairman, Board of Supervisors, San Diego County, 1600 Pacific Highway, San Diego, CA 92101.	Department of Public Works, Flood Control, 5201 Ruffin Road, Suite P, San Diego, CA 92123.	Jan. 29, 2016	060284
Nevada:					
Clark (FEMA Docket No.: B–1552).	City of Henderson (15–09–1109P).	The Honorable Andy A. Hafen, Mayor, City of Henderson, 240 Water Street, Henderson, NV 89015.	Public Works Department, 240 Water Street, Henderson, NV 89015.	Feb. 5, 2016	320005
Clark (FEMA Docket No.: B–1552).	Unincorporated areas of Clark County (15–09–1539P).	The Honorable Steve Sisolak, Chairman, Board of Supervisors, Clark County, 500 South Grand Central Parkway, 6th Floor, Las Vegas, NV 89106.	Office of the Director of Public Works, 500 South Grand Central Parkway, Las Vegas, NV 89155.	Feb. 11, 2016	320003

[FR Doc. 2016–09853 Filed 4–26–16; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4263–DR; Docket ID FEMA–2016–0001]

Louisiana; Amendment No. 5 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Louisiana (FEMA–4263–DR), dated March 13, 2016, and related determinations.

DATES: *Effective Date:* April 7, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Louisiana is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of March 13, 2016.

Avoyelles Parish for Individual Assistance and assistance for debris removal and emergency protective measures (Categories A and B), including direct federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–09872 Filed 4–26–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0002; Internal Agency Docket No. FEMA–B–1616]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before July 26, 2016.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–1616, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *http://floodsrp.org/pdfs/srp_fact_sheet.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: April 12, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

I. Watershed-based studies:

Community	Community map repository address
Upper Saline Watershed	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Grant County, Arkansas, and Incorporated Areas	
City of Sheridan	City Hall, 106 West Bell Street, Sheridan, AR 72150.
Town of Leola	Town Hall, 400 Lee Street, Leola, AR 72084.
Town of Poyen	Town Hall, 111 North Front Street, Poyen, AR 72128.
Town of Prattsville	Mayor's Office, 9251 Highway 270 West, Prattsville, AR 72129.
Town of Tull	Community Center, 8208 North Main Street, Tull, AR 72015.

Community	Community map repository address
Unincorporated Areas of Grant County	Grant County Assessor's Office, 101 West Center Street, Room 102, Sheridan, AR 72150.

II. Non-watershed-based studies:

Community	Community map repository address
Lafayette County, Florida, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 10–04–8512S Preliminary Date: May 27, 2015	
Unincorporated Areas of Lafayette County	Lafayette County Building Department, 120 West Main Street, Mayo, FL 32066.
Brunswick County, North Carolina, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 15–04–A111S Preliminary Date: March 31, 2015	
City of Northwest	Northwest City Hall, 4889 Vernon Road, Leland, NC 28451.
Town of Oak Island	Town Hall, 4601 East Oak Island Drive, Oak Island, NC 28465.
Town of St. James	Town Hall, 4140 A Southport-Supply Road, St. James, NC 28461.
Unincorporated Areas of Brunswick County	Brunswick County Building Inspections Department, 75 Courthouse Drive, Building 1, Bolivia, NC 28422.
Camden County, North Carolina, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 11–04–8218S Preliminary Date: November 30, 2015	
City of Elizabeth City	Planning Department, 302 East Colonial Avenue, Room 308, Elizabeth City, NC 27907.
Unincorporated Areas of Camden County	Camden County Offices, 117 North NC Highway 343, Camden, NC 27921.
Chatham County, North Carolina, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 14–04–A755S Preliminary Date: March 31, 2015	
Unincorporated Areas of Chatham County	Chatham County Planning Department, 80–A East Street, Pittsboro, NC 27312.
Chowan County, North Carolina, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 11–04–8218S Preliminary Date: November 30, 2015	
Town of Edenton	Town Hall, 400 South Broad Street, Edenton, NC 27932.
Unincorporated Areas of Chowan County	Chowan County Planning Department, 108 East King Street, Edenton, NC 27932.
Columbus County, North Carolina, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 15–04–A111S Preliminary Date: March 31, 2015	
Unincorporated Areas of Columbus County	Columbus County Tax Office, 125 Washington Street, Whiteville, NC 28472.

Community	Community map repository address
Currituck County, North Carolina, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 11–04–8218S Preliminary Date: November 30, 2015	
Unincorporated Areas of Currituck County	Currituck County Planning and Inspections Department, 153 Courthouse Road, Currituck, NC 27929.
Durham County, North Carolina, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 11–04–7660S Preliminary Date: March 31, 2015	
City of Durham	City Hall, Public Works Department, 101 City Hall Plaza, Durham, NC 27701.
City of Raleigh	Engineering Department, Municipal Building, 222 West Hargett Street, Raleigh, NC 27601.
Town of Chapel Hill	Stormwater Management Program Office, 208 North Columbia Street, Chapel Hill, NC 27514.
Town of Morrisville	Planning Department, Town Hall, 260 Town Hall Drive, Suite B, Morrisville, NC 27560.
Unincorporated Areas of Durham County	Durham County Stormwater Services Division, 101 City Hall Plaza, Durham, NC 27701.
Franklin County, North Carolina, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 14–04–A755S Preliminary Date: March 31, 2015	
Town of Wake Forest	Planning Department, 301 South Brooks Street, Third Floor, Wake Forest, NC 27587.
Unincorporated Areas of Franklin County	Franklin County Planning and Inspections, 215 East Nash Street, Louisburg, NC 27549.
Granville County, North Carolina, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 11–04–7906S Preliminary Date: March 31, 2015	
City of Creedmoor	Planning and Zoning Department, 111 Masonic Street, Creedmoor, NC 27522.
City of Oxford	Planning Department, 300 Williamsboro Street, Oxford, NC 27565.
Town of Butner	Town Hall, 415 Central Avenue, Butner, NC 27509.
Town of Stem	Town Office, 113 Tally Ho Road, Stem, NC 27581.
Unincorporated Areas of Granville County	Granville County Planning Department, 122 Williamsboro Street, Oxford, NC 27565.
Johnston County, North Carolina, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 14–04–A755S Preliminary Date: March 31, 2015	
Unincorporated Areas of Johnston County	Johnston County Planning Department, 309 East Market Street, Smithfield, NC 27577.
Orange County, North Carolina, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 14–04–A755S Preliminary Date: March 31, 2015	
Town of Chapel Hill	Stormwater Management Program Office, 208 North Columbia Street, Chapel Hill, NC 27514.
Unincorporated Areas of Orange County	Orange County Planning Department, 131 West Margaret Lane, Suite 201, Hillsborough, NC 27278.

Community	Community map repository address
Pasquotank County, North Carolina, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 11–04–8218S Preliminary Date: November 30, 2015	
City of Elizabeth City	Planning Department, 302 East Colonial Avenue, Room 308, Elizabeth City, NC 27907.
Unincorporated Areas of Pasquotank County	Pasquotank County Planning Department, 206 East Main Street, Elizabeth City, NC 27907.
Pender County, North Carolina, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 15–04–A111S Preliminary Date: March 31, 2015	
Town of Watha	Town Hall, 425 Watha Road, Watha, NC 28478.
Unincorporated Areas of Pender County	Pender County Planning Department, 805 South Walker Street, Burgaw, NC 28425.
Perquimans County, North Carolina, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 11–04–8218S Preliminary Date: November 30, 2015	
Town of Hertford	Town Hall, 114 West Grubb Street, Hertford, NC 27944.
Town of Winfall	Town Hall, 100 Park View Lane, Winfall, NC 27985.
Unincorporated Areas of Perquimans County	Perquimans County Inspections Department, 104 Dobbs Street, Hertford, NC 27944.
Person County, North Carolina, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 11–04–7906S Preliminary Date: March 31, 2015	
City of Roxboro	Planning Department, 105 South Lamar Street, Roxboro, NC 27573.
Unincorporated Areas of Person County	Person County Planning and Zoning Department, 325 South Morgan Street, Roxboro, NC 27573.
Robeson County, North Carolina, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 15–04–A111S Preliminary Date: March 31, 2015	
City of Lumberton	Planning Department, 501 East 5th Street, Lumberton, NC 28358.
Unincorporated Areas of Robeson County	Robeson County Inspections and Zoning Department, 435 Caton Road, Lumberton, NC 28360.
Vance County, North Carolina, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 11–04–7906S Preliminary Date: March 31, 2015	
City of Henderson	Planning Department, 134 Rose Avenue, Henderson, NC 27536.
Town of Middleburg	Vance County Planning and Development Office, 156 Church Street, Suite 003, Henderson, NC 27536.
Unincorporated Areas of Vance County	Vance County Planning and Development Office, 156 Church Street, Suite 003, Henderson, NC 27536.
Wake County, North Carolina, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 14–04–9098S Preliminary Date: August 30, 2013	
Town of Cary	Stormwater Services Division, Town Hall, 316 North Academy Street, Cary, NC 27513.
Unincorporated Areas of Wake County	Wake County Environmental Services Department, Waverly F. Akins Office Building, 337 South Salisbury Street, Raleigh, NC 27602.

Community	Community map repository address
Wake County, North Carolina, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 14–04–9706S Preliminary Date: April 30, 2014	
Unincorporated Areas of Wake County	Wake County Environmental Services Department, Waverly F. Akins Office Building, 337 South Salisbury Street, Raleigh, NC 27602.
Wake County, North Carolina, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 11–04–7660S Preliminary Date: March 31, 2015	
City of Raleigh	Engineering Department, Municipal Building, 222 West Hargett Street, Raleigh, NC 27601.
Town of Apex	Engineering Department, 73 Hunter Street, Apex, NC 27502.
Town of Cary	Stormwater Services Division, Town Hall, 316 North Academy Street, Cary, NC 27513.
Town of Fuquay-Varina	Planning Department, Town Hall, 401 Old Honeycutt Road, Fuquay-Varina, NC 27526.
Town of Garner	Engineering Department, 900 Seventh Avenue, Building B, Garner, NC 27529.
Town of Holly Springs	Engineering Department, 128 South Main Street, Holly Springs, NC 27540.
Town of Knightdale	Town Hall, 950 Steeple Square Court, Knightdale, NC 27545.
Town of Morrisville	Planning Department, Town Hall, 260 Town Hall Drive, Suite B, Morrisville, NC 27560.
Town of Rolesville	Planning Department, Town Hall, 502 Southtown Circle, Rolesville, NC 27571.
Town of Wake Forest	Planning Department, 301 South Brooks Street, Third Floor, Wake Forest, NC 27587.
Town of Wendell	Planning Department, 15 East Fourth Street, Wendell, NC 27591.
Town of Zebulon	Planning Department, Town Hall, 1003 North Arendell Avenue, Zebulon, NC 27597.
Unincorporated Areas of Wake County	Wake County Environmental Services Department, Waverly F. Akins Office Building, 337 South Salisbury Street, Raleigh, NC 27602.

[FR Doc. 2016–09839 Filed 4–26–16; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0002]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below.

The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

DATES: The effective date of July 20, 2016 which has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *www.msc.fema.gov* by the effective date indicated above.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov*. The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: April 12, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Hancock County, Maine (All Jurisdictions) **Docket No.: FEMA–B–1415**	
Bald Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Bar Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Beach Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Bear Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Big Barred Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Birch Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Bradbury Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Butter Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Chain Links Islands—North	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Chain Links Islands—South	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Channel Rock Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
City of Ellsworth	City Hall, One City Hall Plaza, Ellsworth, ME 04605.
Colt Head Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Compass Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Crow Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Eagle Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Eaton Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Fling Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Grass Ledge Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Great Spruce Head Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Hardhead Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.

Community	Community map repository address
Hog Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Horsehead Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Inner Porcupine Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Little Barred Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Little Marshall Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Little Spruce Head	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Marshall Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Outer Porcupine Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Peak Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Pickering Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Pond Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Pumpkin Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Resolution Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Scott Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Scrag Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Sheep Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Sloop Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Sloop Island Ledge	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Spectacle Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Sugarloaf	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Town of Amherst	Town Office, 572 Airline Road, Amherst, ME 04605.
Town of Bar Harbor	Town Hall, 93 Cottage Street, Bar Harbor, ME 04609.
Town of Blue Hill	Town Office, 18 Union Street, Blue Hill, ME 04614.
Town of Brooklin	Town Office, 23 Bay Road, Brooklin, ME 04616.
Town of Brooksville	Town Office, One Town House Road, Brooksville, ME 04617.
Town of Bucksport	Town Office, 50 Main Street, Bucksport, ME 04416.
Town of Castine	Emerson Hall, 67 Court Street, Castine, ME 04421.
Town of Cranberry Isles	Cranberry Isles Town Office, 16 Maple Avenue, Islesford, ME 04646.
Town of Dedham	Town Office, 2073 Main Road, Suite A, Dedham, ME 04429.
Town of Deer Isle	Town Office, 70 Church Street, Deer Isle, ME 04627.
Town of Eastbrook	Town Office, 959 Eastbrook Road, Eastbrook, ME 04634.
Town of Franklin	Town Office, 34 Main Street, Franklin, ME 04634.
Town of Frenchboro	Town Office, One Executive Drive, Frenchboro, ME 04635.
Town of Gouldsboro	Gouldsboro Town Office, 59 Main Street, Prospect Harbor, ME 04669.

Community	Community map repository address
Town of Hancock	Town Office, 18 Point Road, Hancock, ME 04640.
Town of Lamoine	Town Hall, 606 Douglas Highway, Lamoine, ME 04605.
Town of Mariaville	Town Office, 1686 Mariaville Road, Mariaville, ME 04605.
Town of Mount Desert	Mount Desert Town Office, 21 Sea Street, Northeast Harbor, ME 04662.
Town of Orland	Town Office, 25 School House Road, Orland, ME 04472.
Town of Otis	Town Office, 132 Otis Road, Otis, ME 04605.
Town of Penobscot	Town Office, One Southern Bay Road, Penobscot, ME 04476.
Town of Sedgwick	Town Office, 719 North Sedgwick Road, Sedgwick, ME 04676.
Town of Sorrento	Town Office, 79 Pomola Avenue, Sorrento, ME 04677.
Town of Southwest Harbor	Town Office, 26 Village Green Way, Southwest Harbor, ME 04679.
Town of Stonington	Town Office, 32 Main Street, Stonington, ME 04681.
Town of Sullivan	Town Office, 1888 US Highway 1, Sullivan, ME 04664.
Town of Surry	Town Office, 741 North Bend Road, Surry, ME 04684.
Town of Swan's Island	Town Office, 125 Harbor Road, Swan's Island, ME 04685.
Town of Tremont	Tremont Town Office, 20 Harbor Drive, Bass Harbor, ME 04653.
Town of Trenton	Town Office, 59 Oak Point Road, Trenton, ME 04605.
Town of Verona Island	Town Hall, 16 School Street, Verona Island, ME 04416.
Town of Waltham	Town Office, 1520 Waltham Road, Waltham, ME 04605.
Town of Winter Harbor	Town Office, 20 School Street, Winter Harbor, ME 04693.
Township of Fletchers Landing	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Township of T07 SD	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Two Bush Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Western Island	Land Use Planning Commission, Maine Department of Agriculture, Conservation and Forestry, 18 Elkins Lane/Harlow Building, 4th floor, State House Station 22, Augusta, ME 04333.
Talbot County, Maryland, and Incorporated Areas **Docket No.: FEMA–B–1359**	
Town of Easton	Town Hall, 14 South Harrison Street, Easton, MD 21601.
Town of Oxford	Municipal Building, 101 Market Street, Oxford, MD 21654.
Town of St. Michaels	Edgar M. Bosley, Jr. Municipal Building, 300 Mill Street, St. Michaels, MD 21663.
Unincorporated Areas of Talbot County	Talbot County Office of Planning and Zoning, 215 Bay Street, Suite 2, Easton, MD 21601.
Dukes County, Massachusetts (All Jurisdictions) **Docket No.: FEMA–B–1523**	
Town of Aquinnah	Town Hall, 65 State Road, Aquinnah, MA 02535.
Town of Chilmark	Town Hall, 401 Middle Road, Chilmark, MA 02535.
Town of Edgartown	Town Hall, 70 Main Street, Edgartown, MA 02539.
Town of Gosnold	Gosnold Town Hall, 28 Tower Hill Road, Cuttyhunk Island, MA 02713.
Town of Oak Bluffs	Town Hall, 56 School Street, Oak Bluffs, MA 02557.
Town of Tisbury	Tisbury Town Hall, 51 Spring Street, Vineyard Haven, MA 02568.
Town of West Tisbury	Town Hall, 1059 State Road, West Tisbury, MA 02575.

[FR Doc. 2016–09854 Filed 4–26–16; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4263–DR; Docket ID FEMA–2016–0001]

Louisiana; Amendment No. 6 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Louisiana (FEMA–4263–DR), dated March 13, 2016, and related determinations.

DATES: *Effective Date:* April 8, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this disaster is closed effective April 8, 2016.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–09835 Filed 4–26–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4262–DR; Docket ID FEMA–2016–0001]

Virginia; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the Commonwealth of Virginia (FEMA–4262–DR), dated March 7, 2016, and related determinations.

DATES: *Effective Date:* April 11, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the Commonwealth of Virginia is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of March 7, 2016.

The counties of Greene, Henrico, and Shenandoah and the independent cities of Fairfax and Fredericksburg for Public Assistance.

The counties of Greene, Henrico, and Shenandoah and the independent cities of Fairfax and Fredericksburg for snow assistance under the Public Assistance program for any continuous 48-hour period during or proximate to the incident period.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2016–09873 Filed 4–26–16; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0002; Internal Agency Docket No. FEMA–B–1603]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before July 26, 2016.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–1603, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *http://floodsrp.org/pdfs/srp_fact_sheet.pdf*.

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: April 12, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Henderson County, Kentucky, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 15–04–8107S Preliminary Date: November 17, 2015	
City of Henderson	City Hall, 222 First Street, Henderson, KY 42419.
Unincorporated Areas of Henderson County	Henderson County Courthouse, 20 North Main Street, Henderson, KY 42420.
Jim Wells County, Texas, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 14–06–0766S Preliminary Date: September 30, 2015	
City of Alice	City Hall, 500 East Main Street, Alice, TX 78332.
City of Premont	City Government Offices, 200 Southwest First Street, Premont, TX 78375.
City of San Diego	City Hall, 404 South Mier Street, San Diego, TX 78384.
Unincorporated Areas of Jim Wells County	County Courthouse, 200 North Almond Street, Alice, TX 78332.
Nueces County, Texas, and Incorporated Areas	
Maps Available for Inspection Online at: *http://www.fema.gov/preliminaryfloodhazarddata*	
Project: 05–06–A088S Preliminary Date: October 23, 2015	
City of Agua Dulce	City Hall, 1514 Second Street, Agua Dulce, TX 78330.
City of Aransas Pass	City Hall, 600 West Cleveland Boulevard, Aransas Pass, TX 78336.
City of Bishop	City Hall, 203 East Main Street, Bishop, TX 78343.
City of Corpus Christi	Development Services, 2406 Leopard Street, Corpus Christi, TX 78408.
City of Driscoll	City Hall, 130 West Avenue D, Driscoll, TX 78351.
City of Petronila	Petronila City Hall, 2475 County Road 69, Robstown, TX 78380.
City of Port Aransas	City Hall, 710 West Avenue A, Port Aransas, TX 78373.
City of Portland	Public Works, 1101 Moore Avenue, Portland, TX 78374.
City of Robstown	Code Enforcement, 201 North 4th Street, Robstown, TX 78380.
Unincorporated Areas of Nueces County	Nueces County Courthouse, 901 Leopard Street, Corpus Christi, TX 78401.

[FR Doc. 2016–09837 Filed 4–26–16; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2016–0002; Internal Agency Docket No. FEMA–B–1619]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The

FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Title 44, part 65 of the Code of Federal Regulations (44 CFR part 65). The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will become effective on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: April 12, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Effective date of modification	Community No.
Connecticut: New Haven.	Town of Madison (15–01–1621P).	Mr. Fillmore McPherson, First Selectman, Town of Madison, Town Office, 8 Campus Drive, Madison, CT 06443.	Town Offices, 8 Campus Drive, Madison, CT 06443.	*http://www.msc.fema.gov/lomc*	July 8, 2016	090079
Idaho: Ada	Unincorporated areas of Ada County (16–10–0348X).	Commissioner Dave Case, Chairman, Board of Commissioners, Ada County, 200 West Front Street, 3rd Floor, Boise, ID 83702.	Ada County Courthouse, 200 West Front Street, Boise, ID 83702.	*http://www.msc.fema.gov/lomc*	June 2, 2016	160001
Illinois:						
McHenry	Village of Fox River Grove (15–05–7970P).	The Honorable Robert J. Nunamaker, Village President, Village of Fox River Grove, 305 Illinois Street, Fox River Grove, IL 60021.	Village Hall, 305 Illinois Street, Fox River Grove, IL 60021.	*http://www.msc.fema.gov/lomc*	July 18, 2016	170477
McHenry	Unincorporated areas of McHenry County (15-05-7970P).	The Honorable Joseph Gottemoller, Chairman, McHenry County Board, County Government Center, 2200 North Seminary Avenue, Woodstock, IL 60098.	County Government Center, 2200 North Seminary Avenue, Woodstock, IL 60098.	*http://www.msc.fema.gov/lomc*	July 18, 2016	170732
Iowa:						

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Effective date of modification	Community No.
Johnson	City of Coralville (15–07–1807P).	The Honorable John Lundell, Mayor, City of Coralville, 1512 7th Street, P.O. Box 5127, Coralville, IA 52241.	City Hall, 1512 7th Street, Coralville, IA 52241.	*http://www.msc.fema.gov/lomc*	June 24, 2016	190169
Johnson	Unincorporated Areas of Johnson County (15–07–1807P).	Mr. Rod Sullivan, Chairperson, Board of Supervisors, Johnson County Administration Building, 913 South Dubuque Street, Suite 204, Iowa City, IA 52240.	Johnson County, Planning and Zoning, 913 South Dubuque Street, Iowa City, IA 52240.	*http://www.msc.fema.gov/lomc*	June 24, 2016	190882
Kansas: Johnson	City of Olathe (16–07–0379P).	The Honorable Michael Copeland, Mayor, City of Olathe, P.O. Box 768, Olathe, KS 66051.	City Hall, Olathe Planning Office, 100 West Santa Fe Drive, Olathe, KS 66061.	*http://www.msc.fema.gov/lomc*	July 15, 2016	200173
Minnesota: Anoka	City of Blaine (15–05–7513P).	The Honorable Tom Ryan, Mayor, City of Blaine, 10801 Town Square Drive Northeast, Blaine, MN 55449.	City Hall Offices, 10801 Town Square Drive Northeast, Blaine, MN 55449.	*http://www.msc.fema.gov/lomc*	July 1, 2016	270007
Clay	City of Moorhead (16–05–0672P).	The Honorable Del Rae Williams, Mayor, City of Moorhead, Moorhead City Hall, 500 Center Avenue, Moorhead, MN 56561.	City Hall, 500 Center Avenue, Moorhead, MN 56561.	http://www.msc.fema.gov/lomc	June 10, 2016	275244
Missouri: Jasper	City of Carthage (15–07–1541P).	The Honorable J. Michael Harris, Mayor, City of Carthage, 326 Grant Street, Carthage, MO 64836.	City Hall, 326 Grant Street, Carthage, MO 64836.	*http://www.msc.fema.gov/lomc*	July 8, 2016	290181
Jasper	Unincorporated areas of Jasper County (15–07–1541P).	Mr. John Bartosh, Jasper County Commissioner, 302 South Main Street, Room 101, Carthage, MO 64836.	Jasper County Courthouse, 302 South Main Street, Carthage, MO 64836.	*http://www.msc.fema.gov/lomc*	July 8, 2016	290807
New York: Dutchess.	Town of Wappinger (16–02–0187P).	The Honorable Lori A. Jiava, Supervisor, Town of Wappinger, Town Hall, 20 Middlebush Road, Wappinger Falls, NY 12590.	Town Hall, 20 Middlebush Road, Wappinger Falls, NY 12590.	*http://www.msc.fema.gov/lomc*	September 2, 2016.	361387
Oregon: Lane	City of Creswell (16–10–0415X).	The Honorable Dave Stram, Mayor, City of Creswell, 13 South 1st Street, P.O. Box 276, Creswell, OR 97426.	City Hall, 13 South 1st Street, Creswell, OR 97426.	*http://www.msc.fema.gov/lomc*	July 5, 2016	410121
Lane	Unincorporated Areas of Lane County (16–10–0415X).	The Honorable Faye Stewart, Commissioner, East Lane County, Lane County Public Service Building, 125 East 8th Street, Eugene, OR 97401.	Lane County Planning Department, Public Service Building, 125 East 8th Street, Eugene, OR 97401.	*http://www.msc.fema.gov/lomc*	July 5, 2016	415591
Tennessee: Hamblen.	City of Morristown (15–04–8338P).	The Honorable Gary Chesney, Mayor, City of Morristown, 100 West First North Street, P.O. Box 1499, Morristown, TN 37816.	County Courthouse, 511 West Second North Street, Morristown, TN 37814.	*http://www.msc.fema.gov/lomc*	May 27, 2016	470070
Wisconsin: Eau Claire.	Unincorporated areas of Eau Claire (15–05–5833P).	Mr. Gregg Moore, County Board Chair, Eau Claire County, 721 Oxford Avenue, Eau Claire, WI 54703.	County Courthouse, 721 Oxford Avenue, Eau Claire, WI 54703.	*http://www.msc.fema.gov/lomc*	July 5, 2016	555552

[FR Doc. 2016–09816 Filed 4–26–16; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0049]

Agency Information Collection Activities: Request for Verification of Naturalization, Form N–25; Extension, Without Change, of a Currently Approved Collection

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 60-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration (USCIS) invites the general public and other Federal agencies to comment upon this proposed extension of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until June 27, 2016.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0049 in the subject box, the agency name and Docket ID USCIS–2005–0036. To avoid duplicate submissions, please use only *one* of the following methods to submit comments:

(1) *Online.* Submit comments via the Federal eRulemaking Portal Web site at *http://www.regulations.gov* under e-Docket ID number USCIS–2005–0036;

(2) *Email.* Submit comments to *USCISFRComment@uscis.dhs.gov;*

(3) *Mail.* Submit written comments to DHS, USCIS, Office of Policy and Strategy, Chief, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529–2140.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Acting Chief, 20 Massachusetts Avenue NW., Washington, DC 20529–2140, telephone number 202–272–8377 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at *http://www.uscis.gov,* or call the USCIS National Customer Service Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments:

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2005–0036 in the search box. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension, Without Change, of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Request for Verification of Naturalization.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* N–25; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* State, local or Tribal Government. This form will allow U.S. Citizenship and Immigration Services (USCIS) to obtain verification from the courts that a person claiming to be a naturalized citizen has, in fact, been naturalized.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection N–25 is 1,000 and the estimated hour burden per response is .25 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 250 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $500.00.

Dated: April 21, 2016.

Samantha Deshommes,

Acting Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2016–09787 Filed 4–26–16; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5913–N–09]

60-Day Notice of Proposed Information Collection: Applications for Housing Assistance Payments; Special Claims Processing

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested

parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: Comments Due Date: June 27, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Lanier M. Hylton, Housing Program Manager, Office of Program Systems Management, Office of Multifamily Housing Programs, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410, telephone (202) 402–2510 (this is not a toll free number) for copies of the proposed forms and other available information. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Applications for Housing Assistance Payments; Special Claims Processing.

OMB Approval Number: 2502–0182.

Type of Request: Revision or extension of currently approved collection.

Form Number(s): HUD 52670–A part 5, HUD–52671–C, HUD 52671–A, HUD–52671–D, 52670–A–PART–1, HUD 52671–B, HUD–52670, HUD 52670–A part 3, HUD–52670–A part 4, HUD 52670–A Part 2

Description of the need for the information and proposed use: HUD's Office of Multifamily Housing Programs needs to collect this information in order to establish an applicant's eligibility for admittance to subsidized housing, specify which eligible applicants may be given priority over others, and prohibit racial discrimination in conjunction with selection of tenants and unit assignments.

HUD must specify tenant eligibility requirements as well as how tenants' incomes, rents and assistance must be verified and computed so as to prevent HUD from making improper payments to owners on behalf of assisted tenants. These information collections are essential to ensure the reduction of improper payments standard in providing $9.5 billion in rental assistance to low-income families in HUD Multifamily properties.

a. These collections are authorized by the following statutes:

- Section 8 (42 U.S.C. 1437 *et seq.*).
- Rent Supplement (12 U.S.C. 1701s).
- Rental Assistance Payments (12 U.S.C. 1715z–1).
- Section 236 (12 U.S.C. 1172z–1).
- Section 221(d) (3) Below Market Interest Rate (12 U.S.C. 1715l).
- Title VI of the Civil Rights Act of 1964.
- Title VIII of the Civil Rights Act of 1968, as amended (Section 808).
- Executive Order 11063, Equal Opportunity in Housing.
- Social Security Numbers (42 U.S.C. 3543).
- Section 562 of the Housing and Community Development Act of 1987.
- Section 202 of the Housing Act of 1959, as amended.
- Section 811 of the National Affordable Housing Act of 1980.
- Computer Matching and Privacy Protection Act of 1988 (102 Statute 2507).
- Privacy Act of 1974 (5 U.S.C. 552a), Records Maintained on Individuals.
- Quality Housing and Work Responsibility Act of 1998 (QHWRA).
- Section 658 of Title VI of Subtitle D of the Housing and Community Development Act of 1992.
- Executive Order 13520 of November 20, 2009, The Improper Payments Elimination and Recovery Act (IPERA).
- Executive Order 13515 of October 14, 2009, Increasing Participation of Asian Americans and Pacific Islanders in Federal Programs.

b. These collections are covered by the following regulations:

- Section 8: 24 CFR part 5, 24 CFR 880, 24 CFR 884, 24 CFR 886, 24 CFR 891 Subpart E.
- Section 236 and Rental Assistance Payments: 24 CFR 236.
- Section 221(d) (3): 24 CFR 221.
- Racial, Sex, Ethnic Data: 24 CFR 121.
- Nondiscrimination and Equal Opportunity in Housing: 24 CFR 107.
- Nondiscrimination in Federal Programs: 24 CFR 1.
- Social Security Numbers: 24 CFR part 5.
- Procedures for Obtaining Wage and Claim Information Agencies: 24 CFR part 760.
- Implementation of the Privacy Act of 1974: 24 CFR part 16.
- Mandated use of HUD's Enterprise Income Verification (EIV) System: 24 CFR 5.233.

Respondents (*i.e.* affected public):

- Performance Based Contract Administrators
- Contract Administrators
- Owners and Property Management Agents
- State Housing Finance Agencies
- Public Housing Authorities (PHA)
- The Government Accountability Office
- U. S. Census Bureau
- Office of Management and Budget (OMB)
- Congress/Public Requests (Under FOIA)

Estimated Number of Respondents: 25,843.

Estimated Number of Responses: 322,116.

Frequency of Response: 12 per annum.

Average Hours per Response: 1.33.

Total Estimated Burden: 372,497.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: April 21, 2016.

Janet M. Golrick,

Associate General Deputy Assistant Secretary for Housing—Associate Deputy Federal Housing Commissioner.

[FR Doc. 2016–09868 Filed 4–26–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNV912000 L13400000.PQ0000 LXSS0006F0000; 12–08807; MO# 4500092196; TAS: 14X1109]

Notice of Public Meetings: Mojave-Southern Great Basin Resource Advisory Council, Nevada

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meetings.

SUMMARY: In accordance with the Federal Land Policy and Management Act (FLPMA) and the Federal Advisory Committee Act of 1972 (FACA), the U.S. Department of the Interior, Bureau of Land Management (BLM) Mojave-Southern Great Basin Resource Advisory Council (RAC), will hold three meetings in Nevada in fiscal year 2016. The meetings are open to the public.

DATES: May 19, and Sept. 22, 2016. Meeting times will be published in local and regional media sources at least 14 days before each meeting. All meetings will include a public comment period.

ADDRESSES: The May 19 meeting will be held at the Toll Brothers Clubhouse, 3190 Mantua Village, Henderson, Nevada; Aug. 9–10, Caliente Railroad Depot, 100 Depot Ave., Caliente, Nevada. The Sept. 22 meeting will be held at the Nye County Commission Chambers, 2100 E. Walt Williams Dr., Pahrump, Nevada.

FOR FURTHER INFORMATION CONTACT: Chris Hanefeld, Public Affairs Specialist, Ely District Office, 702 N. Industrial Way, Ely, NV 89301, telephone: (775) 289–1842, email: *chanefel@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The 15-member Council advises the Secretary of the Interior, through the BLM, on a variety of planning and management issues associated with public land management in Nevada. Topics for discussion at each meeting will include, but are not limited to:

- May 19 (Henderson)—Sloan Canyon National Conservation Area, and Southern Nevada Public Land Management Act.
- Aug. 9–10 (Caliente)—Ash Springs Recreation Site, Basin and Range National Monument, and Greater Sage-Grouse.
- September 22 (Pahrump)—Target Shooting on Public Lands, and Wild Horses.

Managers' reports of district office activities will be given at each meeting. The Council may raise other topics at the meetings.

Final agendas will be posted on-line at the BLM Mojave-Southern Great Basin RAC Web site at *http://www.blm.gov/nv/st/en/res/resource_advisory.html* and will be published in local and regional media sources at least 14 days before each meeting. Individuals who need special assistance such as sign language interpretation or other reasonable accommodations, or who wish to receive a copy of each agenda, may contact Chris Hanefeld no later than 10 days prior to each meeting.

Rudy Evenson,

Deputy Chief, Office of Communications.

[FR Doc. 2016–09788 Filed 4–26–16; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWO350000/L1910000.BK0000/LRCMP5RXE004; 16XL1109AF; MO#4500091788]

Notice of Filing of Plats of Survey; Montana

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing of plats of survey.

SUMMARY: The Bureau of Land Management (BLM) will file the plat of survey of the lands described below in the BLM Montana State Office, Billings, Montana, on May 27, 2016.

DATES: A notice of protest of the survey must be filed before May 27, 2016 to be considered. A statement of reasons for a protest may be filed with the notice of protest and must be filed within 30 days after the notice of protest is filed.

ADDRESSES: Protests of the survey should be sent to the Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669.

FOR FURTHER INFORMATION CONTACT: Thomas Trzinski, Cadastral Surveyor, Branch of Cadastral Survey, Bureau of Land Management, 5001 Southgate Drive, Billings, Montana 59101–4669, telephone (406) 896–5364 or (406) 896–5003, *ttrzinsk@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: This survey was executed at the request of the Bureau of Indian Affairs, Rocky Mountain Region, Billings, Montana, and was necessary to determine individual and tribal trust lands.

The lands we surveyed are:

Principal Meridian, Montana

T. 33 N., Rs. 55 and 56 E.

The plat, in two sheets, representing the dependent resurvey of a portion of the north boundary of the Fort Peck Indian Reservation, a portion of the west boundary (R.56E), a portion of the subdivisional lines, and the adjusted original meanders of the former left and right banks of Big Muddy Creek, (identical with the meanders of the present left and right banks of Big Muddy Creek), through section 7 and the survey of the medial line of Big Muddy Creek, and certain partition lines, Township 33 North, Ranges 55 and 56 East, Principal Meridian, Montana, was accepted March 24, 2016. We will place a copy of the plat, in two sheets, and related field notes we described in the open files. They will be available to the public as a matter of information. If the BLM receives a protest against this survey, as shown on this plat, in two sheets, prior to the date of the official filing, we will stay the filing pending our consideration of the protest. We will not officially file this plat, in two sheets, until the day after we have accepted or dismissed all protests and they have become final, including decisions or appeals. Before including your address, phone number, email address, or other personally identifying information in your comment, you should be aware that your entire comment—including your personally identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personally identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 43 U.S.C. Chap. 3.

Joshua F. Alexander,

Acting Chief, Branch of Cadastral Survey, Division of Energy, Minerals and Realty.

[FR Doc. 2016–09533 Filed 4–26–16; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

Office of Natural Resources Revenue

[Docket No. ONRR–2016–0001; DS63610000 DR2000000.CH7000 167D0102R2]

Temporary Physical Address Change for General Ledger Team

AGENCY: Office of Natural Resources Revenue, Interior.

ACTION: Notice.

SUMMARY: ONRR is temporarily changing its physical address for courier services and personal deliveries.

DATES: Effective April 13, 2016.

FOR FURTHER INFORMATION CONTACT: Darrel Redford, Supervisory Accountant, at (303) 231–3085, or email at *Darrel.Redford@onrr.gov.*

SUPPLEMENTARY INFORMATION: Effective April 13, 2016, all courier services and personal deliveries should be made to ONRR at the Denver Federal Center, Building 53, entrance E–20. Visitor parking is available near entrance E–20, with a phone to request entry. Call Armando Salazar at (303) 231–3585 or Janet Giron at (303) 231–3088 to gain entrance.

Dated: April 11, 2016.

Gregory J. Gould,

Director, Office of Natural Resources Revenue.

[FR Doc. 2016–09850 Filed 4–26–16; 8:45 am]

BILLING CODE 4335–30–P

DEPARTMENT OF THE INTERIOR

Office of Natural Resources Revenue

[Docket No. ONRR–2011–0018; DS63610000 DR2PS0000.CH7000 167D0102R2]

Notice of Proposed Audit Delegation Renewal for the States of Alaska, California, Colorado, North Dakota, Texas, Utah, and Wyoming

AGENCY: Office of the Secretary, Office of Natural Resources Revenue (ONRR), Interior.

ACTION: Notice.

SUMMARY: The States of Alaska, California, Colorado, North Dakota, Texas, Utah, and Wyoming are requesting that ONRR renew current delegations of audit and investigation authority. This notice gives members of the public an opportunity to review and comment on the States' proposals.

DATES: Submit written comments on or before May 27, 2016.

ADDRESSES: You may submit comments on this notice by any of the following methods:

- Electronically go to *http://www.regulations.gov.* In the entry titled "Enter Keyword or ID," enter ONRR–2011–0018, and then click search. Follow the instructions to submit public comments. ONRR will post all comments.
- Email comments to Luis Aguilar, Regulatory Specialist, at *Luis.Aguilar@onrr.gov.* Please reference the Docket No. ONRR–2011–0018 in your comments.
- Hand-carry comments or use an overnight courier service. Our courier address is Building 85, Room A–614, Denver Federal Center, West 6th Ave. and Kipling St., Denver, Colorado 80225. Please reference the Docket No. ONRR–2011–0018 in your comments.

FOR FURTHER INFORMATION CONTACT: Ms. Heidi Badaracco, State and Tribal Support, State and Indian Coordination, ONRR; telephone (303) 231–3434; or by email at *Heidi.Badaracco@onrr.gov.*

SUPPLEMENTARY INFORMATION: The following officials are the State contacts for their respective proposals:

State	Department	Contact information
Alaska	Division of Oil and Gas	Monica French, 550 West 7th Avenue, Suite 800, Anchorage, AK 99501–5313.
California	State Controller's Office	Elizabeth Gonzalez, 300 Capitol Mall, Suite 518, Sacramento, CA 94250–5874.
Colorado	Colorado Department of Revenue, Mineral Audit Section.	Brenda Petersen, 720 S. Colorado Blvd., Suite 400N, Denver, CO 80246–1968.
North Dakota	State Auditor's Office, Royalty Audit Section	Dennis Roller, 425 North 5th Street—3rd Floor, Bismarck, ND 58501–4033.
Texas	Texas General Land Office	Luke Decker, 1700 N. Congress Ave., Suite 640, Austin, TX 78701–1436.
Utah	Utah State Tax Commission	Jennifer Casady, 210 North 1950 West, Salt Lake City, Utah 64134–9000.
Wyoming	WY Dept. of Audit, Mineral Audit Division	Steve Dilsaver, 122 West 25th Street, Cheyenne, WY 82001–3004.

The States' new agreement application, including proposed budget and work plan, are due April 1, 2016. In accordance with 30 CFR 1227.101(b)(1), the States request that ONRR delegate the royalty management functions of conducting audits and investigations. The States request delegation of these functions for producing Federal oil and gas leases within the State boundaries, as applicable. This is for producing Federal oil and gas leases in the Outer Continental Shelf, subject to revenue sharing under 8(g) of the Outer Continental Shelf Lands Act, 43 U.S.C. 1337(g); and for other producing solid mineral or geothermal Federal leases within the State. The States do not request delegation of royalty and production reporting functions. In addition to audit and investigation authority, the State of Wyoming also requests to renew its authority under 30 CFR 1227.101(b)(2) to issue Orders to Pay, Orders to Perform, and tolling agreements as a result of an audit or compliance review; it also requests to renew its subpoena authority under the Royalty Simplification and Fairness Act related to oil and gas revenues owed to the United States and shared with the State, which are attributable to leased Federal onshore property within the State.

The States have asked ONRR to renew the delegations within the time required by 30 CFR 1227.110(b). The States of Alaska, California, and Utah request 100-percent funding of the delegated functions for a 3-year period beginning July 1, 2016, with the opportunity to extend for an additional 3-year period. The States of Colorado, North Dakota, Texas, and Wyoming request 100-

percent funding of the delegated functions for a 3-year period beginning October 1, 2016, with the opportunity to extend for an additional 3-year period. The States have a current audit delegation agreement with ONRR, as shown in the table below:

State	Agreement No.	Term
Alaska	D12AC70003	7/01/2010–6/30/2013 7/01/2013–6/30/2016.
California	D12AC70004	7/01/2010–6/30/2013 7/01/2013–6/30/2016.
Colorado	D12AC70005	10/01/2010–9/30/2013 10/01/2013–9/30/2016.
North Dakota	D12AC70007	10/01/2010–9/30/2013 10/01/2013–9/30/2016.
Texas	D12AC70009	10/01/2010–9/30/2013 10/01/2013–9/30/2016.
Utah	D12AC70010	7/01/2010–6/30/2013 7/01/2013–6/30/2016.
Wyoming	D12AC70012	10/01/2010–9/30/2013 10/01/2013–9/30/2016.

Therefore, ONRR has determined that we will not hold a formal hearing for comments under 30 CFR 1227.105.

Dated: April 22, 2016.

Gregory J. Gould,

Director, Office of Natural Resources Revenue.

[FR Doc. 2016–09852 Filed 4–26–16; 8:45 am]

BILLING CODE 4335–30–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[OMB Control Number 1010–0176; MMAA104000]

Information Collection: Renewable Energy and Alternate Uses of Existing Facilities on the Outer Continental Shelf; Submitted for OMB Review; Comment Request

ACTION: 30-Day notice.

SUMMARY: To comply with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Ocean Energy Management (BOEM) is notifying the public that we have submitted an information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval. This ICR concerns the paperwork requirements in the regulations under "Renewable Energy and Alternate Uses of Existing Facilities on the Outer Continental Shelf." This notice provides the public a second opportunity to comment on the paperwork burden of this collection.

DATES: Submit written comments by May 27, 2016.

ADDRESSES: Submit comments on this ICR to the Desk Officer for the Department of the Interior at OMB–OIRA at (202) 395–5806 (fax) or *OIRA_submission@omb.eop.gov.* Please provide a copy of your comments to BOEM at OPRA Mail Stop: VA–DIR, 45600 Woodland Road, Sterling, VA 20166. Please reference ICR 1010–0176 in your comment and include your name and return address.

FOR FURTHER INFORMATION CONTACT: Office of Policy, Regulations, and Analysis at or (202) 208–6352. You may review the ICR online at *http://www.reginfo.gov.* Follow the instructions to review Department of the Interior collections under review by OMB.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 1010–0176.

Title: 30 CFR 585, Renewable Energy and Alternate Uses of Existing Facilities on the Outer Continental Shelf.

Forms: BOEM–0002, BOEM–0003, BOEM–0004, BOEM–0005, BOEM–0006.

Abstract: The Outer Continental Shelf (OCS) Lands Act, as amended (43 U.S.C. 1331 *et seq.* and 43 U.S.C. 1801 *et seq.*), authorizes the Secretary of the Interior to issue leases, easements, or rights-of-way on the OCS for activities that produce or support production, transportation, or transmission of energy from sources other than oil and gas (renewable energy). Specifically, subsection 8(p) of the OCS Lands Act, as amended (43 U.S.C. 1337(p)), directs the Secretary of the Interior to issue any necessary regulations to carry out the OCS renewable energy program. The Secretary delegated this authority to BOEM. BOEM has issued regulations for OCS renewable energy activities at 30 CFR part 585; this notice concerns the reporting and recordkeeping elements required by these regulations.

Respondents operate commercial and noncommercial technology projects that include installation, construction, operation and maintenance, and decommissioning of offshore facilities, as well as possible onshore support facilities. BOEM must ensure that these activities and operations on the OCS are performed in a safe manner which do not cause damage to the environment or endanger life or health, do not interfere with the rights of other users on the OCS, and balance the protection and development of OCS resources. Therefore, BOEM needs information concerning the proposed activities, facilities, safety equipment, inspections and tests, and natural and manmade hazards near the site, as well as assurance of fiscal responsibility.

BOEM uses forms to collect some information to ensure proper and efficient administration of OCS renewable energy leases and grants and to document the financial responsibility of lessees and grantees. Forms BOEM–0002, BOEM–0003, BOEM–0004, and BOEM–0006 are used by renewable energy entities on the OCS to assign a lease interest, designate an operator, and to assign or relinquish a lease or grant. Form BOEM–0005 was designed to guarantee the performance of sureties with respect to bonds issued on behalf of OCS renewable energy lessees, grantees, and operators. BOEM maintains the submitted forms as official lease and grant records pertaining to operating responsibilities, ownership, and financial responsibility.

We will protect information considered proprietary under the Freedom of Information Act (5 U.S.C. 552) and its implementing regulations (43 CFR part 2) and under regulations at 30 CFR 585.113, addressing disclosure of data and information to be made available to the public and others. No items of a sensitive nature are collected. Responses are mandatory or required to obtain a benefit.

Frequency: On occasion or annually.

Description of Respondents: Companies interested in renewable energy-related uses on the OCS and holders of leases and grants under 30 CFR part 585.

Estimated Reporting and Recordkeeping Hour Burden: The estimated annual hour burden for this collection is 25,688 hours. The following table details the individual components and estimated hour burdens. In calculating the burdens, we assumed that respondents perform certain requirements in the normal course of their activities. We consider these to be usual and customary and took that into account in estimating the burden.

BURDEN TABLE

Section(s) in 30 CFR 585	Reporting and recordkeeping requirement [1]	Hour burden	Non-hour cost burdens	
			Average number of annual responses	Annual burden hours
	Subpart A—General Provisions			
102; 105; 110	These sections contain general references to responsibilities, submitting comments, requests, applications, plans, notices, reports, and/or supplemental information for BOEM approval—burdens covered under specific requirements.			0
102(e)	State and local governments enter into task force or joint planning or coordination agreement with BOEM.	1	2 agreements	2
103; 904	Request general departures not specifically covered elsewhere in part 585..	2	6 requests	12
105(c)	Make oral requests or notifications and submit written follow up within 3 business days not specifically covered elsewhere in part 585.	1	5 requests	5
106; 107; 213(e); 230(f); 302(a); 408(b)(7); 409(c); 1005(d); 1007(c); 1013(b)(7).	Submit evidence of qualifications to hold a lease or grant; submit required supporting information (electronically if required).	2	20 submissions	40
106(b)(1)	Request exception from exclusion or disqualification from participating in transactions covered by Federal non-procurement debarment and suspension system.	1	1 exception	1
106(b)(2); 118(c); 225(b); 436; 437; 527(c); 705(c)(2); 1016.	Request reconsideration and/or hearing	Requirement not considered IC under 5 CFR 1320.3(h)(9).		0
108; 530(b)	Notify BOEM within 3 business days after learning of any action filed alleging respondent is insolvent or bankrupt.	1	1 notice	1
109	Notify BOEM in writing of merger, name change, or change of business form no later than 120 days after earliest of either the effective date or filing date.	Requirement not considered IC under 5 CFR 1320.3(h)(1).		0
111	Within 30 days of receiving bill, submit processing fee payments for BOEM document or study preparation to process applications and other requests.	.5	4 submissions	2
		4 payments × $4,000 = $16,000		
111(b)(2), (3)	Submit comments on proposed processing fee or request approval to perform or directly pay contractor for all or part of any document, study, or other activity, to reduce BOEM processing costs.	2	4 requests	8
111(b)(3)	Perform, conduct, develop, etc., all or part of any document, study, or other activity; and provide results to BOEM to reduce BOEM processing fee.	19,000	1 submission	19,000
111(b)(3)	Pay contractor for all or part of any document, study, or other activity, and provide results to BOEM to reduce BOEM processing costs.	3 contractor payments × $950,000 = $2,850,000		

BURDEN TABLE—Continued

Section(s) in 30 CFR 585	Reporting and recordkeeping requirement[1]	Hour burden	Non-hour cost burdens	
			Average number of annual responses	Annual burden hours
111(b)(7); 118(a); 436(c)	Appeal BOEM estimated processing costs, decisions, or orders pursuant to 30 CFR 590.	Exempt under 5 CFR 1320.4(a)(2), (c).		0
113(b)	Respond to the Freedom of Information Act release schedule.	4	1 agreement	4
115(c)	Request approval to use later edition of a document incorporated by reference or alternative compliance.	1	1 request	1
116	The Director may occasionally request information to administer and carry out the offshore renewable energy program via **Federal Register** Notices.	4	25 submissions	100
118(c); 225(b)	Within 15 days of bid rejection, request reconsideration of bid decision or rejection.	Requirement not considered IC under 5 CFR 1320.3(h)(9).		0
Subtotal			71 responses	19,176
			$2,866,000 non-hour costs	
Subpart B—Issuance of OCS Renewable Energy Leases				
200; 224; 231; 235; 236; 238.	These sections contain references to information submissions, approvals, requests, applications, plans, payments, etc., the burdens for which are covered elsewhere in part 585.			0
210; 211(a–c); 212 thru 216.	Submit nominations and general comments in response to **Federal Register** notices on Request for Interest in OCS Leasing, Call for Information and Nominations (Call), Area Identification, and Notices of Sale. Includes industry, State & local governments.	Not considered IC as defined in 5 CFR 1320.3(h)(4).		0
210; 211(a–c); 212 thru 216.	Submit comments and required information in response to **Federal Register** notices on Request for Interest in OCS Leasing, Call for Information and Nominations (Call), Area Identification, and Notices of Sale. Includes industry, State & local governments.	4	30 comments	120
211(d); 216; 220 thru 223; 231(c)(2).	Submit bid, payments, and required information in response to **Federal Register** Final Sale Notice.	5	12 bids	60
224	Within 10 business days, execute 3 copies of lease form and return to BOEM with required payments, including evidence that agent is authorized to act for bidder; if applicable, submit information to support delay in execution—competitive leases.	1	2 lease executions	2
230; 231(a)	Submit unsolicited request and acquisition fee for a commercial or limited lease.	5	2 requests	10
231(b)	Submit comments in response to **Federal Register** notice re interest of unsolicited request for a lease.	4	4 comments	16
231(g)	Within 10 business days of receiving lease documents, execute lease; file financial assurance and supporting documentation—noncompetitive leases.	2	2 leases	4
231(g)	Within 45 days of receiving lease copies, submit rent and rent information.	Burdens covered by information collections approved for ONRR 30 CFR Chapter XII.		0
235(b); 236(b)	Request additional time to extend preliminary or site assessment term of commercial or limited lease, including revised schedule for SAP, COP, or GAP submission.	1	3 requests	3
237(b)	Request lease be dated and effective 1st day of month in which signed.	1	1 request	1

BURDEN TABLE—Continued

Section(s) in 30 CFR 585	Reporting and recordkeeping requirement[1]	Hour burden	Non-hour cost burdens	
			Average number of annual responses	Annual burden hours
238	Submit other renewable energy research activities ...	Burden covered under SAPs & GAPs § 585.600(a), (c).		0
Subtotal			56 responses	216
Subpart C—ROW Grants and RUE Grants for Renewable Energy Activities				
306; 309; 315; 316	These sections contain references to information submissions, approvals, requests, applications, plans, payments, etc., the burdens for which are covered elsewhere in part 585.			0
302(a); 305; 306	Submit copies of a request for a new or modified ROW or RUE and required information, including qualifications to hold a grant, in format specified.	5	1 request	5
307; 308(a)(1)	Submit information in response to **Federal Register** notice of proposed ROW or RUE grant area or comments on notice of grant auction.	4	2 comments	8
308(a)(2), (b); 315; 316	Submit bid and payments in response to **Federal Register** notice of auction for a ROW or RUE grant.	5	1 bid	5
309	Submit decision to accept or reject terms and conditions of noncompetitive ROW or RUE grant.	2	1 submission	2
Subtotal			5 responses	20
Subpart D—Lease and Grant Administration				
400; 401; 402; 405; 409; 416, 433.	These sections contain references to information submissions, approvals, requests, applications, plans, payments, etc., the burdens for which are covered elsewhere in part 585.			0
401(b)	Take measures directed by BOEM in cessation order and submit reports in order to resume activities.	100	1 report	100
405(d)	Submit written notice of change of address	Requirement not considered IC under 5 CFR 1320.3(h)(1).		0
405(e); Form BOEM–0006.	If designated operator (DO) changes, notify BOEM and identify new DO for BOEM approval.	1	1 notice	1
408 thru 411; Forms BOEM–0002 and BOEM–0003.	Within 90 days after last party executes a transfer agreement, submit copies of a lease or grant assignment application, including originals of each instrument creating or transferring ownership of record title, eligibility and other qualifications; and evidence that agent is authorized to execute assignment, in format specified.	1 (30 minutes per form × 2 forms = 1 hour).	2 requests/submissions.	2
415(a)(1); 416; 420(a), (b); 428(b).	Submit request for suspension and required information/payment no later than 90 days prior to lease or grant expiration.	10	1 request	10
417(b)	Conduct, and if required pay for, site-specific study to evaluate cause of harm or damage; and submit copies of study and results, in format specified.	100	1 study/submission	100
		1 study × $950,000 = $950,000		
425 thru 428; 652(a); 235(a), (b).	Request lease or grant renewal no later than 180 days before termination date of your limited lease or grant, or no later than 2 years before termination date of operations term of commercial lease. Submit required information.	6	1 requests	6
435; 658(c)(2); Form BOEM–0004.	Submit copies of application to relinquish lease or grant, in format specified.	1	1 submission	1

BURDEN TABLE—Continued

Section(s) in 30 CFR 585	Reporting and recordkeeping requirement[1]	Hour burden	Non-hour cost burdens	
			Average number of annual responses	Annual burden hours
436; 437	Provide information for reconsideration of BOEM decision to contract or cancel lease or grant area.	Requirement not considered IC under 5 CFR 1320.3(h)(9).		0
Subtotal			8 responses	220
			$950,000 non-hour costs	
Subpart E—Payments and Financial Assurance Requirements				
An * indicates the primary cites for providing bonds or other financial assurance, and the burdens include any previous or subsequent references throughout part 585 to furnish, replace, or provide additional bonds, securities, or financial assurance (including riders, cancellations, replacements). This subpart contains references to other information submissions, approvals, requests, applications, plans, etc., the burdens for which are covered elsewhere in part 585. In the future BOEM may require electronic filings of certain submissions.				0
500 thru 509; 1011	Submit payor information, payments and payment information, and maintain auditable records according to ONRR regulations or guidance.	Burdens covered by information collections approved for ONRR 30 CFR Chapter XII.		0
506(c)(4)	Submit documentation of the gross annual generation of electricity produced by the generating facility on the lease—use same form as authorized by the EIA.	Burden covered under DOE/EIA OMB Control Number 1905–0129.		0
510; 506(c)(3)	Submit application and required information for waiver or reduction of rental or other payment.	1	1 submission	1
*515; 516; 525(a) thru (f).	Execute and provide $100,000 minimum lease-specific bond or other approved security; or increase bond level if required.	1	2 bonds	2
*516(a)(2), (3), (b), (c); 517; 525(a) thru (f).	Execute and provide commercial lease supplemental bonds in amounts determined by BOEM.	1	2 bonds	2
516(a)(4); 521(c)	Execute and provide decommissioning bond or other financial assurance; schedule for providing the appropriate amount.	1	1 bond	1
517(c)(1)	Submit comments on proposed adjustment to bond amounts.	1	1 submission	1
517(c)(2)	Request bond reduction and submit evidence to justify.	5	1 request	5
*520; 521; 525(a) thru (f); Form BOEM–0005.	Execute and provide $300,000 minimum limited lease or grant-specific bond or increase financial assurance and required information.	1	1 bond	1
525(g)	Surety notice to lessee or ROW/RUE grant holder and BOEM within 5 business days after initiating surety insolvency or bankruptcy proceeding, or Treasury decertifies surety.	1	1 surety notice	1
*526 Form BOEM–0005	In lieu of surety bond, pledge other types of securities, including authority for BOEM to sell and use proceeds and submit required information (1 hour for form).	2	1 pledge	2
526(c)	Provide annual certified statements describing the nature and market value, including brokerage firm statements/reports.	1	1 statement	1
*527; 531	Demonstrate financial worth/ability to carry out present and future financial obligations, annual updates, and related or subsequent actions/records/reports, etc.	10	1 demonstration	10

BURDEN TABLE—Continued

Section(s) in 30 CFR 585	Reporting and recordkeeping requirement[1]	Hour burden	Non-hour cost burdens	
			Average number of annual responses	Annual burden hours
528	Provide third-party indemnity; financial information/statements; additional bond info; executed guarantor agreement and supporting information/documentation/agreements.	10	1 submission	10
528(c)(6); 532(b)	Guarantor/Surety requests BOEM terminate period of liability and notifies lessee or ROW/RUE grant holder, etc.	1	1 request	1
* 529	In lieu of surety bond, request authorization to establish decommissioning account, including written authorizations and approvals associated with account.	2	1 request	2
530	Notify BOEM promptly of lapse in bond or other security/action filed alleging lessee, surety or guarantor et al is insolvent or bankrupt.	1	1 notice	1
533(a)(2)(ii), (iii)	Provide agreement from surety issuing new bond to assume all or portion of outstanding liabilities.	3	1 submission	3
536(b)	Within 10 business days following BOEM notice, lessee, grant holder, or surety agrees to and demonstrates to BOEM that lease will be brought into compliance.	16	1 demonstration every 2 years.	8
Subtotal			21 responses	52
Subpart F—Plans and Information Requirements				
Two ** indicate the primary cites for Site Assessment Plans (SAPs), Construction and Operations Plans (COPs), and General Activities Plans (GAPs); and the burdens include any previous or subsequent references throughout part 585 to submission and approval. This subpart contains references to other information submissions, approvals, requests, applications, plans, etc., the burdens for which are covered elsewhere in part 585.				0
** 600(a); 601(a), (b); 605 thru 614; 238; 810.	Within time specified after issuance of a competitive lease or grant, or within time specified after determination of no competitive interest, submit copies of SAP, including required information to assist BOEM to comply with NEPA/CZMA such as hazard info, air quality, SEMS, and all required information, certifications, requests, etc., in format specified.	240	2 SAPs	480
** 600(b); 601(c), (d)(1); 606(b); 618; 620 thru 629; 632; 633; 810.	If requesting an operations term for commercial lease, within time specified before the end of site assessment term, submit copies of COP, or FERC license application, including required information to assist BOEM to comply with NEPA/CZMA such as hazard info, air quality, SEMS, and all required information, surveys and/or their results, reports, certifications, project easements, supporting data and information, requests, etc., in format specified.	1,000	2 COPs	2,000
** 600(c); 601(a), (b); 640 thru 648; 651; 238; 810.	Within time specified after issuance of a competitive lease or grant, or within time specified after determination of no competitive interest, submit copies of GAP, including required information to assist BOEM to comply with NEPA/CZMA such as hazard info, air quality, SEMS, and all required information, surveys and reports, certifications, project easements, requests, etc., in format specified.	240	2 GAP	480
** 601(d)(2); 622; 628(f); 632; 634; 658(c)(3); 907.	Submit revised or modified COPs, including project easements, and all required additional information.	50	1 revised or modified COP.	50

BURDEN TABLE—Continued

Section(s) in 30 CFR 585	Reporting and recordkeeping requirement[1]	Hour burden	Non-hour cost burdens	
			Average number of annual responses	Annual burden hours
602[2]	Until BOEM releases financial assurance, respondents must maintain, and provide to BOEM if requested, all data and information related to compliance with required terms and conditions of SAP, COP, or GAP.	2	9 records/submissions	18
** 613(a), (d), (e); 617	Submit revised or modified SAPs and required additional information.	50	1 revised or modified SAP.	50
612; 647	Submit copy of SAP or GAP consistency certification and supporting documentation, including noncompetitive leases.	1	2 leases	2
615(a)	Notify BOEM in writing within 30 days of completion of construction and installation activities under SAP.	1	2 notices	2
615(b)	Submit annual report summarizing findings from site assessment activities.	30	4 reports	120
615(c)	Submit annual, or at other time periods as BOEM determines, SAP compliance certification, effectiveness statement, recommendations, reports, supporting documentation, etc.	40	4 certifications	160
617(a)	Notify BOEM in writing before conducting any activities not approved, or provided for, in SAP; provide additional information if requested.	10	1 notice	10
627(c)	Submit oil spill response plan as required by BSEE 30 CFR part 254.	Burden covered under BSEE 1014–0007.		0
631	Request deviation from approved COP schedule	2	1 request	2
633(b)	Submit annual, or at other time periods as BOEM determines, COP compliance certification, effectiveness statement, recommendations, reports, supporting documentation, etc.	50	9 certifications	450
634(a)	Notify BOEM in writing before conducting any activities not approved or provided for in COP, and provide additional information if requested.	10	1 notice	10
635	Notify BOEM any time commercial operations cease without an approved suspension.	1	1 notice	1
636(a)	Notify BOEM in writing no later than 30 days after commencing activities associated with placement of facilities on lease area.	1	2 notices	2
636(b)	Notify BOEM in writing no later than 30 days after completion of construction and installation activities.	1	2 notices	2
636(c)	Notify BOEM in writing at least 7 days before commencing commercial operations.	1	1 notices	1
** 642(b); 648; 655; 658(c)(3).	Submit revised or modified GAPs and required additional information.	50	1 revised or modified GAP.	50
651	Before beginning construction of OCS facility described in GAP, complete survey activities identified in GAP and submit initial findings. [This only includes the time involved in submitting the findings; it does not include the survey time as these surveys would be conducted as good business practice.].	30	2 surveys/reports	60

BURDEN TABLE—Continued

Section(s) in 30 CFR 585	Reporting and recordkeeping requirement[1]	Hour burden	Non-hour cost burdens	
			Average number of annual responses	Annual burden hours
653(a)	Notify BOEM in writing within 30 days of completing installation activities under the GAP.	1	2 notices	2
653(b)	Submit annual report summarizing findings from activities conducted under approved GAP.	30	4 reports	120
653(c)	Submit annual, or at other time periods as BOEM determines, GAP compliance certification, recommendations, reports, etc.	40	4 certifications	160
655(a)	Notify BOEM in writing before conducting any activities not approved or provided for in GAP, and provide additional information if requested.	10	1 notice	10
656	Notify BOEM any time approved GAP activities cease without an approved suspension.	1	1 notice	1
658(c)(1)	If after construction, cable or pipeline deviate from approved COP or GAP, notify affected lease operators and ROW/RUE grant holders of deviation and provide BOEM evidence of such notices.	3	1 notice/evidence	3
659	Determine appropriate air quality modeling protocol, conduct air quality modeling, and submit 3 copies of air quality modeling report and 3 sets of digital files as supporting information to plans.	70	5 reports/information	350
Subtotal			68 responses	4,596
Subpart G—Facility Design, Fabrication, and Installation				
Three *** indicate the primary cites for the reports discussed in this subpart, and the burdens include any previous or subsequent references throughout part 585 to submitting and obtaining approval. This subpart contains references to other information submissions, approvals, requests, applications, plans, etc., the burdens for which are covered elsewhere in part 585.				0
*** 700(a)(1), (b), (c); 701.	Submit Facility Design Report, including copies of the cover letter, certification statement, and all required information (1–3 paper or electronic copies as specified).	200	1 report	200
*** 700(a)(2), (b), (c); 702.	Submit copies of a Fabrication and Installation Report, certification statement and all required information, in format specified.	160	1 report	160
705(a)(3); 707; 712	Certified Verification Agent (CVA) conducts independent assessment of the facility design and submits copies of all reports/certifications to lessee or grant holder and BOEM—interim reports if required, in format specified.	100	1 interim report	100
		100	1 final report	100
705(a)(3); 708; 709; 710; 712.	CVA conducts independent assessments/inspections on the fabrication and installation activities, informs lessee or grant holder if procedures are changed or design specifications are modified; and submits copies of all reports/certifications to lessee or grant holder and BOEM—interim reports if required, in format specified.	100	1 interim report	100
		100	1 final report	100
*** 703; 705(a)(3); 712; 815.	CVA/project engineer monitors major project modifications and repairs and submits copies of all reports/certifications to lessee or grant holder and BOEM—interim reports if required, in format specified.	20	1 interim report	20
		15	1 final report	15

BURDEN TABLE—Continued

Section(s) in 30 CFR 585	Reporting and recordkeeping requirement[1]	Hour burden	Non-hour cost burdens	
			Average number of annual responses	Annual burden hours
705(c)	Request waiver of CVA requirement in writing; lessee must demonstrate standard design and best practices.	40	1 waiver	40
706	Submit for approval with SAP, COP, or GAP, initial nominations for a CVA or new replacement CVA nomination, and required information.	16	2 nominations	32
708(b)(2)	Lessee or grant holder notify BOEM if modifications identified by CVA/project engineer are accepted.	1	1 notice	1
709(a)(14); 710(a)(2), (e)[2].	Make fabrication quality control, installation towing, and other records available to CVA/project engineer for review (retention required by § 585.714).	1	3 records retention	3
713	Notify BOEM within 10 business days after commencing commercial operations.	1	1 notice	1
714[2]	Until BOEM releases financial assurance, compile, retain, and make available to BOEM and/or CVA the as-built drawings, design assumptions/analyses, summary of fabrication and installation examination records, inspection results, and records of repairs not covered in inspection report. Record original and relevant material test results of all primary structural materials; retain records during all stages of construction.	100	1 lessee	100
Subtotal			17 responses	972
Subpart H—Environmental and Safety Management, Inspections, and Facility Assessments for Activities Conducted Under SAPs, COPs, and GAPs				
801(c), (d)	Notify BOEM if endangered or threatened species, or their designated critical habitat, may be in the vicinity of the lease or grant or may be affected by lease or grant activities.	1	2 notices	2
801(e), (f)	Submit information to ensure proposed activities will be conducted in compliance with the Endangered Species Act (ESA) and Marine Mammal Protection Act (MMPA); including agreements and mitigating measures designed to avoid or minimize adverse effects and incidental take of endangered species or critical habitat.	6	2 submissions	12
802; 902(e)	Notify BOEM of archaeological resource within 72 hours of discovery.	3	1 notice	3
802(b), (c)	If requested, conduct further archaeological investigations and submit report/information.	10	1 report	10
802(d)	If applicable, submit payment for BOEM costs in carrying out National Historic Preservation Act responsibilities.	.5	1 payment	1
803	If required, conduct additional surveys to define boundaries and avoidance distances and submit report.	15	2 survey/report	30
*** 810; 614; 627; 632(b); 651.	Submit safety management system description with the SAP, COP, or GAP.	35	2 submissions	70
813(b)(1)	Report within 24 hours when any required equipment taken out of service for more than 12 hours; provide written confirmation if reported orally.	.5	2 reports	1
		1	1 written confirmation	1

BURDEN TABLE—Continued

Section(s) in 30 CFR 585	Reporting and recordkeeping requirement [1]	Hour burden	Non-hour cost burdens	
			Average number of annual responses	Annual burden hours
813(b)(3)	Notify BOEM when equipment returned to service; provide written confirmation if reported orally.	.5	2 notices	1
815(c)	When required, analyze cable, P/L, or facility damage or failures to determine cause and as soon as available submit comprehensive written report.	1.5	1 report	2
816	Submit plan of corrective action report on observed detrimental effects on cable, P/L, or facility within 30 days of discovery; take remedial action and submit report of remedial action within 30 days after completion.	2	1 plan/report	2
822(a)(2)(iii), (b)	Maintain records of design, construction, operation, maintenance, repairs, and investigation on or related to lease or ROW/RUE area; make available to BOEM for inspection.	1	4 records retention	4
823	Request reimbursement within 90 days for food, quarters, and transportation provided to BOEM reps during inspection.	2	1 request	2
824(a) [2]	Develop annual self-inspection plan covering all facilities; retain with records, and make available to BOEM upon request.	24	2 plans	48
824(b)	Conduct annual self-inspection and submit report by November 1.	36	2 reports	72
825	Based on API RP 2A–WSD, perform assessment of structures, initiate mitigation actions for structures that do not pass assessment process, retain information, and make available to BOEM upon request.	60	2 assessments/actions.	120
830(a), (c); 831 thru 833	Immediately report incidents to BOEM via oral communications, submit written follow-up report within 15 business days after the incident, and submit any required additional information.	Oral .5	2 incidents	1
		Written 4	1 incident	4
830(d)	Report oil spills as required by BSEE 30 CFR 254	Burden covered under BSEE 1014–0007		0
Subtotal			32 responses	386
Subpart I—Decommissioning				
Four **** indicate the primary cites for the reports discussed in this subpart, and the burdens include any previous or subsequent references throughout part 585 to submitting and obtaining approval. This subpart contains references to other information submissions, approvals, requests, applications, plans, etc., the burdens for which are covered elsewhere in part 585.				
**** 902; 905, 906; 907; 908(c); 909.	Submit for approval, in format specified, copies of the SAP, COP, or GAP decommissioning application and site clearance plan at least 2 years before decommissioning activities begin, 90 days after completion of activities, or 90 days after cancellation, relinquishment, or other termination of lease or grant. Include documentation of coordination efforts w/States/CZMA agencies, local or tribal governments, requests that certain facilities remain in place for other activities, be converted to an artificial reef, or be toppled in place. Submit additional information/evidence requested or modify and resubmit application.	20	1 application	20
902(d); 908	Notify BOEM at least 60 days before commencing decommissioning activities.	1	1 notice	1

BURDEN TABLE—Continued

Section(s) in 30 CFR 585	Reporting and recordkeeping requirement [1]	Hour burden	Non-hour cost burdens	
			Average number of annual responses	Annual burden hours
910	Within 60 days after removing a facility, verify to BOEM that site is cleared.	1	1 verification	1
912	Within 60 days after removing a facility, cable, or pipeline, submit a written report.	8	1 report	8
BOEM does not anticipate decommissioning activities for at least 5 years so the requirements have been given a minimal burden.				
Subtotal			4 responses	30
Subpart J—RUEs for Energy- and Marine-Related Activities Using Existing OCS Facilities				
1004, 1005, 1006	Contact owner of existing facility and/or lessee of the area to reach preliminary agreement to use facility and obtain concurring signatures; submit request to BOEM for an alternative use RUE, including all required information/modifications.	1	1 request	1
1007(a), (b), (c)	Submit indication of competitive interest in response to **Federal Register** notice.	4	1 submission	4
1007(c)	Submit description of proposed activities and required information in response to **Federal Register** notice of competitive offering.	5	1 submission	5
1007(f)	Lessee or owner of facility submits decision to accept or reject proposals deemed acceptable by BOEM.	1	1 submission	1
1010(c)	Request renewal of Alternate Use RUE	6	1 request	6
1012; 1016(b)	Provide financial assurance as BOEM determines in approving RUE for an existing facility, including additional security if required.	1	1 submission	1
1013	Submit request for assignment of an alternative use RUE for an existing facility, including all required information.	1	1 request	1
1015	Request relinquishment of RUE for an existing facility.	1	1 request	1
Subtotal			8 responses	20
Total Burden			290 responses	25,688
			$3,816,000 Non-Hour Cost Burdens	

[1] In the future, BOEM may require electronic filing of certain submissions.

[2] Retention of these records is usual and customary business practice; the burden is primarily to make them available to BOEM and CVAs.

Estimated Reporting and Recordkeeping Non-Hour Cost Burden: The estimated non-hour cost burdens total $3,816,000. The non-hour cost burdens consist of service fees for BOEM document/study preparation, costs for paying a contractor instead of BOEM, and costs for a site-specific study and report to evaluate the cause of harm to natural resources.

Public Disclosure Statement: The PRA (44 U.S.C. 3501, *et seq.*) provides that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. Until OMB approves a collection of information, you are not obligated to respond.

Comments: Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3501, *et seq.,*) requires each agency ". . . to provide notice . . . and otherwise consult with members of the public and affected agencies concerning each proposed collection of information . . ." Agencies must specifically solicit comments to: (a) Evaluate whether the collection is necessary or useful; (b) evaluate the accuracy of the burden of the proposed collection of information; (c) enhance the quality, usefulness, and clarity of the information to be collected; and (d) minimize the burden on the respondents, including the use of technology.

To comply with the public consultation process, on December 17, 2015, BOEM published a **Federal Register** notice (80 FR 78756) announcing that we would submit this ICR to OMB for approval. This notice provided the required 60-day comment period. BOEM received no comments.

Public Availability of Comments: Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: March 7, 2016.

Deanna Meyer-Pietruszka,

Chief, Office of Policy, Regulations and Analysis.

[FR Doc. 2016–09709 Filed 4–26–16; 8:45 am]

BILLING CODE 4310–MR–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–986]

Certain Diaper Disposal Systems and Components Thereof, Including Diaper Refill Cassettes; Notice of Commission Determination Not To Review an Initial Determination Granting Complainants' Motion To Amend the Complaint and the Notice of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination ("ID") (Order No. 7) issued by the presiding administrative law judge ("ALJ") on April 8, 2016, granting the complainants' unopposed motion to amend the complaint and notice of investigation to add two respondents.

FOR FURTHER INFORMATION CONTACT: Robert Needham, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 708–5468. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on February 29, 2016, based on a complaint filed by Edgewell Personal Care Brands, LLC, of Chesterfield, Missouri, and International Refills Company, Ltd., of Christ Church, Barbados (collectively, "Complainants"). 81 *FR* 10277–78. The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 ("section 337"), in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain diaper disposal systems and components thereof, including diaper refill cassettes, by reason of infringement of certain claims of U.S. Patent Nos. 6,974,029 and 8,899,420. *Id.* at 10277. The Commission's notice of investigation named as respondents Munchkin, Inc., of Van Nuys, California; Munchkin Baby Canada Ltd., of Brampton, Canada; and Lianyungang Brilliant Daily Products Co. Ltd., of Lianyungang, China. *Id.* at 10278. The Office of Unfair Import Investigations is not participating in this investigation. *Id.*

On March 31, 2016, Complainants filed an unopposed motion to amend the complaint and the notice of investigation in order to add two respondents: Lianyungang Rainbow Daily Products Co., Ltd., of Lianyungang, China; and Munchkin Asia Limited, of Hong Kong, China. Complainants argue that they learned through discovery that these parties are involved in the manufacture and/or sale for importation of the accused products in this investigation.

On April 8, 2016, the ALJ issued the subject ID and granted Complainants' motion to amend the complaint and the notice of investigation. No petitions for review were filed.

The Commission has determined not to review the subject ID.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: April 22, 2016.

William R. Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2016–09827 Filed 4–26–16; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Antitrust Division

United States v. Len Blavatnik; Proposed Final Judgment and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), that a proposed Final Judgment, Stipulation, and Competitive Impact Statement have been filed with the United States District Court for the District of Columbia in *United States of America* v. *Len Blavatnik*, Civil Action No. 1:15–cv–01631–RDM. On October 6, 2015, the United States filed a Complaint alleging that Len Blavatnik violated the premerger notification and waiting period requirements of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15 U.S.C. 18a, with respect to his acquisition of voting securities of TangoMe, Inc. The proposed Final Judgment, filed at the same time as the Complaint, requires Blavatnik to pay a civil penalty of $656,000.

Copies of the Complaint, proposed Final Judgment, and Competitive Impact Statement are available for inspection on the Antitrust Division's Web site at *http://www.justice.gov/atr* and at the Office of the Clerk of the United States District Court for the District of Columbia. Copies of these materials may be obtained from the Antitrust Division upon request and payment of the copying fee set by Department of Justice regulations.

Public comment is invited within 60 days of the date of this notice. Such comments, including the name of the submitter, and responses thereto, will be posted on the Antitrust Division's Web site, filed with the Court, and, under certain circumstances, published in the **Federal Register**. Comments should be directed to Daniel P. Ducore, Special Attorney, c/o Federal Trade Commission, 600 Pennsylvania Avenue NW., CC–8416, Washington, DC 20580 (telephone: 202–326–2526; email: *dducore@ftc.gov*).

Patricia A. Brink,

Director of Civil Enforcement.

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA c/o Department of Justice, Washington, D.C. 20530, Plaintiff, v. LEN BLAVATNIK c/o Access Industries, 28 Kensington Church Street, 4th Floor, London, United Kingdom W8 4EP, Defendant.

CASE NO.: 1:15–cv–01631

JUDGE: Randolph D. Moss

FILED: 10/06/2015

COMPLAINT FOR CIVIL PENALTIES FOR FAILURE TO COMPLY WITH THE PREMERGER REPORTING AND WAITING REQUIREMENTS OF THE HART-SCOTT-RODINO ACT

The United States of America, Plaintiff, by its attorneys, acting under the direction of the Attorney General of the United States and at the request of the Federal Trade Commission, brings this civil antitrust action to obtain monetary relief in the form of civil penalties against Defendant Len Blavatnik ("Blavatnik"). Plaintiff alleges as follows:

NATURE OF THE ACTION

1. Blavatnik violated the notice and waiting period requirements of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15 U.S.C. 18a ("HSR Act" or "Act"), with respect to the acquisition of voting securities of TangoMe, Inc. ("TangoMe") in August 2014.

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter of this action pursuant to Section 7A(g) of the Clayton Act, 15 U.S.C. 18a(g), and pursuant to 28 U.S.C. 1331, 1337(a), 1345, and 1355 and over the Defendant by virtue of Defendant's consent, in the Stipulation relating hereto, to the maintenance of this action and entry of the Final Judgment in this District.

3. Venue is properly based in this District by virtue of Defendant's consent, in the Stipulation relating hereto, to the maintenance of this action and entry of the Final Judgment in this District.

THE DEFENDANT

4. Defendant Blavatnik is a natural person with his principal office and place of business care of Access Industries, 28 Kensington Church Street, 4th Floor, London, United Kingdom W8 4EP. Blavatnik is engaged in commerce, or in activities affecting commerce, within the meaning of Section 1 of the Clayton Act, 15 U.S.C. 12, and Section 7A(a)(1) of the Clayton Act, 15 U.S.C. 18a(a)(1). At all times relevant to this complaint, Blavatnik had sales or assets in excess of $151.7 million. Blavatnik is the ultimate parent entity of Access Industries ("Access").

OTHER ENTITIES

5. TangoMe is a corporation organized under the laws of Delaware with its principal place of business at 475 Ellis Street, Mountain View, CA 94043. TangoMe is engaged in commerce, or in activities affecting commerce, within the meaning of Section 1 of the Clayton Act, 15 U.S.C. 12, and Section 7A(a)(1) of the Clayton Act, 15 U.S.C. 18a(a)(1). At all times relevant to this complaint, TangoMe had sales or assets in excess of $15.2 million.

6. LyondellBasell Industries N.V. ("LyondellBasell") is a corporation organized under the laws of The Netherlands with its principal place of business at 1221 McKinney Street, Suite 700, Houston, TX 77010. LyondellBasell is engaged in commerce, or in activities affecting commerce, within the meaning of Section 1 of the Clayton Act, 15 U.S.C. 12, and Section 7A(a)(1) of the Clayton Act, 15 U.S.C. 18a(a)(1). At all times relevant to this complaint, LyondellBasell had sales or assets in excess of $12.7 million.

THE HART-SCOTT-RODINO ACT AND RULES

7. The HSR Act requires certain acquiring persons and certain persons whose voting securities or assets are acquired to file notifications with the federal antitrust agencies and to observe a waiting period before consummating certain acquisitions of voting securities or assets. 15 U.S.C. 18a(a) and (b). These notification and waiting period requirements apply to acquisitions that meet the HSR Act's thresholds, which are adjusted annually. During the period of 2014 pertinent to this complaint, the HSR Act's reporting and waiting period requirements applied to transactions that would result in the acquiring person holding more than $75.9 million, if certain sales and asset thresholds were met, and all transactions (regardless of the size of the acquiring or acquired persons) where the acquiring person would hold more than $303.4 million of the acquired person's voting securities and/or assets, except for certain exempted transactions.

8. The HSR Act's notification and waiting period are intended to give the federal antitrust agencies prior notice of, and information about, proposed transactions. The waiting period is also intended to provide the federal antitrust agencies with an opportunity to investigate a proposed transaction and to determine whether to seek an injunction to prevent the consummation of a transaction that may violate the antitrust laws.

9. Pursuant to Section (d)(2) of the HSR Act, 15 U.S.C. 18a(d)(2), rules were promulgated to carry out the purposes of the HSR Act. 16 CFR 801–803 ("HSR Rules"). The HSR Rules, among other things, define terms contained in the HSR Act.

10. Pursuant to section 801.13(a)(1) of the HSR Rules, 16 CFR 801.13(a)(1), "all voting securities of [an] issuer which will be held by the acquiring person after the consummation of an acquisition"—including any held before the acquisition—are deemed held "as a result of" the acquisition at issue.

11. Pursuant to sections 801.13(a)(2) and 801.10(c)(1) of the HSR Rules, 16 CFR 801.13(a)(2) and 801.10(c)(1), the value of publicly traded voting securities already held is the market price, defined to be the lowest closing price within 45 days prior to the subsequent acquisition.

12. Section 7A(g)(1) of the Clayton Act, 15 U.S.C. 18a(g)(1), provides that any person, or any officer, director, or partner thereof, who fails to comply with any provision of the HSR Act is liable to the United States for a civil penalty for each day during which such person is in violation. For violations occurring on or after February 10, 2009, the maximum amount of civil penalty is $16,000 per day, pursuant to the Debt Collection Improvement Act of 1996, Public Law 104–134, 31001(s) (amending the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. 2461 note), and Federal Trade Commission Rule 1.98, 16 CFR 1.98, 74 FR 857 (Jan. 9, 2009).

DEFENDANT'S PRIOR VIOLATION OF THE HSR ACT

13. On August 23, 2010, Blavatnik acquired 133,400 voting securities of LyondellBasell. At the time of the acquisition, Blavatnik already held voting securities of LyondellBasell. The value of the voting securities held by Blavatnik after the acquisition was approximately $634 million.

14. Although he was required to do so, Blavatnik did not file under the HSR Act prior to acquiring LyondellBasell voting securities on August 23, 2010.

15. Blavatnik continued to acquire LyondellBasell voting securities in August and September of 2010, acquiring a total of 3,270,500 additional voting securities.

16. On December 1, 2010, Access, acting on Blavatnik's behalf, made a corrective filing under the HSR Act for the August 23, 2010, acquisition of LyondellBasell voting securities, and the subsequent acquisitions in August and September of 2010. In a letter accompanying the corrective filing, Blavatnik acknowledged that the transaction was reportable under the HSR Act, but asserted that the failure to file and observe the waiting period was inadvertent. Blavatnik also committed that he and Access would consult with HSR counsel before making any

additional acquisitions of voting securities.

17. On January 4, 2011, the Premerger Notification Office of the Federal Trade Commission sent a letter to Access indicating that it would not recommend a civil penalty action regarding the August 23, 2010, LyondellBasell acquisition, but stating that Blavatnik "still must bear responsibility for compliance with the Act. In addition, he is accountable for instituting an effective program to ensure full compliance with the Act's requirements."

VIOLATION

18. On August 6, 2014, Blavatnik, through Access, acquired 2,818,182 shares of TangoMe voting securities. Blavatnik's voting securities represented approximately 29.1% of TangoMe's outstanding voting securities and were valued at approximately $228 million.

19. Prior to acquiring the TangoMe voting securities, neither Access nor Blavatnik conducted any HSR review of the proposed acquisition or consulted with HSR counsel, notwithstanding their commitments to do so made in connection with the LyondellBasell corrective filing.

20. On December 17, 2014, Blavatnik made a corrective filing under the HSR Act for the August 6, 2014, acquisition of TangoMe voting securities. The waiting period on the corrective filing expired on January 16, 2015.

21. Blavatnik was in continuous violation of the HSR Act from August 6, 2014, when it acquired the TangoMe voting securities valued in excess of the HSR Act's $75.9 million size-of-transaction threshold, through January 16, 2015, when the waiting period expired.

REQUEST FOR RELIEF

Wherefore, Plaintiff requests:

a. That the Court adjudge and decree that Defendant Blavatnik's acquisition of TangoMe voting securities on August 6, 2014, was a violation of the HSR Act, 15 U.S.C. 18a; and that Defendant Blavatnik was in violation of the HSR Act each day from August 6, 2014, through January 16, 2015.

b. That the Court order Defendant Blavatnik to pay to the United States an appropriate civil penalty as provided by the HSR Act, 15 U.S.C. 18a(g)(1), the Debt Collection Improvement Act of 1996, Public Law 104–134, 31001(s) (amending the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. 2461 note), and Federal Trade Commission Rule 1.98, 16 CFR 1.98, 74 FR 857 (Jan. 9, 2009).

c. That the Court order such other and further relief as the Court may deem just and proper.

d. That the Court award the Plaintiff its costs of this suit.

Dated: October 6, 2015

FOR THE PLAINTIFF UNITED STATES OF AMERICA:

/s/ ____________________________
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/s/ ____________________________
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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, Plaintiff, v. LEN BLAVATNIK, Defendant.

CASE NO.: 1:15–cv–01631
JUDGE: Randolph D. Moss
FILED: 04/20/2016

COMPETITIVE IMPACT STATEMENT

The United States, pursuant to the Antitrust Procedures and Penalties Act ("APPA"), 15 U.S.C. 16(b)–(h), files this Competitive Impact Statement to set forth the information necessary to enable the Court and the public to evaluate the proposed Final Judgment that would terminate this civil antitrust proceeding.

I. NATURE AND PURPOSE OF THIS PROCEEDING

On October 6, 2015, the United States filed a Complaint against Defendant Len Blavatnik ("Blavatnik"), related to Blavatnik's acquisition of voting securities of TangoMe Inc. ("TangoMe") in 2014. The Complaint alleges that Blavatnik violated Section 7A of the Clayton Act, 15 U.S.C. 18a, commonly known as the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the "HSR Act"). The HSR Act states that "no person shall acquire, directly or indirectly, any voting securities of any person" exceeding certain thresholds until that person has filed pre-acquisition notification and report forms with the Department of Justice and the Federal Trade Commission (collectively, the "federal antitrust agencies" or "agencies") and the post-filing waiting period has expired.[1] The purpose of the notification and waiting period is to allow the agencies an opportunity to conduct an antitrust review of proposed transactions before they are consummated.

The Complaint alleges that Blavatnik, via an entity he controls, acquired voting securities of TangoMe in excess of the statutory threshold ($75.9 million at the time of acquisition) without making the required pre-acquisition filings with the agencies and without observing the waiting period, and that Blatvatnik and TangoMe each met the statutory size of person threshold at the time of the acquisition (Blavatnik and TangoMe had sales or assets in excess of $151.7 million and $15.2 million, respectively).

The Complaint further alleges that Blavatnik previously violated the HSR Act's notification requirements when he acquired shares in LyondellBasell Industries N.V. ("LyondellBasell") in 2010. In August and September of 2010, Blavatnik made several acquisitions of LyondellBasell voting securities without making appropriate HSR filings and observing the required waiting periods. On December 1, 2010, Blavatnik made a corrective filing for these acquisitions. In a letter accompanying the corrective filing, Blavatnik acknowledged that these transactions were reportable under the HSR Act, but asserted that the failure to file and observe the waiting period was inadvertent. Blavatnik also committed that he would consult with HSR counsel before making any additional acquisitions of voting securities. On January 4, 2011, the Premerger Notification Office of the Federal Trade Commission sent a letter to Blavatnik indicating that it would not recommend a civil penalty action regarding the 2010 LyondellBasell acquisition, but stated that Blavatnik would be "accountable for instituting an effective program to ensure full compliance with the [HSR] Act's requirements."[2]

At the same time the Complaint was filed, the United States also filed a Stipulation and proposed Final Judgment that eliminates the need for a trial in this case. The proposed Final

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[1] 15 U.S.C. 18a(a).

[2] Complaint, ¶ 17.

Judgment is designed to deter Blavatnik's HSR Act violations. Under the proposed Final Judgment, Blavatnik must pay a civil penalty in the amount of $656,000.

The United States and the Defendant have stipulated that the proposed Final Judgment may be entered after compliance with the APPA, unless the United States first withdraws its consent. Entry of the proposed Final Judgment would terminate this case, except that the Court would retain jurisdiction to construe, modify, or enforce the provisions of the proposed Final Judgment and punish violations thereof. Entry of this judgment would not constitute evidence against, or an admission by, any party with respect to any issue of fact or law involved in the case and is conditioned upon the Court's finding that entry is in the public interest.

II. DESCRIPTION OF THE EVENTS GIVING RISE TO THE ALLEGED VIOLATIONS OF THE ANTITRUST LAWS

A. Len Blavatnik and the Acquisitions of TangoMe Voting Securities

Len Blavatnik is a British businessman, investor, and philanthropist. In 1986, Blavatnik founded Access Industries ("Access"), a private international conglomerate company located in New York. Access, in turn, controls multiple entities engaged in three primary industries: natural resources and chemicals; media and telecommunications; and real estate.

TangoMe is a California based technology start-up known largely for its smartphone application *Tango*. With approximately 200 million registered users, *Tango* is a messaging app offering free video calls, texting, and photo sharing.

On August 6, 2014, Blavatnik, through Access, acquired shares of TangoMe voting securities. Blavatnik's voting securities represented approximately 29.1% of TangoMe's outstanding voting securities and were valued at approximately $228 million. This exceeded the HSR Act's $75.9 million size-of-transaction threshold then in effect.

Prior to acquiring the TangoMe voting securities, neither Access nor Blavatnik conducted any HSR review of the proposed acquisition or consulted with HSR counsel, notwithstanding Blavatnik's commitments made in connection with the 2010 LyondellBasell corrective filing. Blavatnik became aware of the missed HSR filing when Access conducted a periodic review of the company-wide holdings of TangoMe. After discovering the missed filing, Blavatnik promptly made a corrective filing on December 17, 2014. The waiting period expired on January 16, 2015.

B. Blavatnik's Violation of HSR

As alleged in the Complaint, Blavatnik acquired in excess of the $75.9 million in voting securities of TangoMe without complying with the pre-acquisition notification and waiting period requirements of the HSR Act. Blavatnik's failure to comply undermined the statutory scheme and the purpose of the HSR Act. Blavatnik's December 17, 2014, corrective filing included a letter acknowledging that the acquisitions were reportable under the HSR Act.

III. EXPLANATION OF THE PROPOSED FINAL JUDGMENT

The proposed Final Judgment imposes a $656,000 civil penalty designed to deter this Defendant and others from violating the HSR Act. The United States adjusted the penalty downward from the maximum because the violation was unintentional, the Defendant promptly self-reported the violation after discovery, and the Defendant is willing to resolve the matter by consent decree and avoid prolonged investigation and litigation. The penalty also reflects Defendant's previous violation of the HSR Act after pledging to consult counsel in order to prevent such violations. The United States expects this penalty to deter Blavatnik and others from violating the HSR Act. The relief will have a beneficial effect on competition because the agencies will be properly notified of acquisitions, in accordance with the law. At the same time, the penalty will not have any adverse effect on competition.

IV. REMEDIES AVAILABLE TO POTENTIAL PRIVATE LITIGANTS

There is no private antitrust action for HSR Act violations; therefore, entry of the proposed Final Judgment will neither impair nor assist the bringing of any private antitrust action.

V. PROCEDURES AVAILABLE FOR MODIFICATION OF THE PROPOSED FINAL JUDGMENT

The United States and Defendant have stipulated that the proposed Final Judgment may be entered by this Court after compliance with the provision of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry of the decree upon this Court's determination that the proposed Final Judgment is in the public interest.

The APPA provides a period of at least sixty (60) days preceding the effective date of the proposed Final Judgment within which any person may submit to the United States written comments regarding the proposed Final Judgment. Any person who wishes to comment should do so within sixty (60) days of the date of publication of this Competitive Impact Statement in the **Federal Register**, or the last date of publication in a newspaper of the summary of this Competitive Impact Statement, whichever is later. All comments received during this period will be considered by the United States, which remains free to withdraw its consent to the proposed Final Judgment at any time prior to entry. The comments and the response of the United States will be filed with the Court. In addition, comments will be posted on the U.S. Department of Justice, Antitrust Division's internet Web site and, under certain circumstances, published in the **Federal Register**. Written comments should be submitted to:

Daniel P. Ducore
Special Attorney, United States
c/o Federal Trade Commission,
600 Pennsylvania Avenue NW.,
CC–8416
Washington, DC 20580
Email: *dducore@ftc.gov*

The proposed Final Judgment provides that this Court retains jurisdiction over this action, and the parties may apply to this Court for any order necessary or appropriate for the modification, interpretation, or enforcement of the Final Judgment.

VI. ALTERNATIVES TO THE PROPOSED FINAL JUDGMENT

As an alternative to the proposed Final Judgment, the United States considered pursuing a full trial on the merits against the Defendant. The United States is satisfied, however, that the proposed relief is an appropriate remedy in this matter. Given the facts of this case, including the Defendant's self-reporting of the violation and willingness to settle quickly, the United States is satisfied that the proposed civil penalty is sufficient to address the violation alleged in the Complaint and to deter violations by similarly situated entities in the future, without the time, expense, and uncertainty of a full trial on the merits.

VII. STANDARD OF REVIEW UNDER THE APPA FOR THE PROPOSED FINAL JUDGMENT

The APPA requires that remedies contained in proposed consent judgments in antitrust cases brought by the United States be subject to a sixty (60) day comment period, after which the court shall determine whether entry of the proposed Final Judgment is "in the public interest." 15 U.S.C. 16(e)(1). In making that determination, the court, in accordance with the statute as amended in 2004, is required to consider:

> (A) the competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and
>
> (B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. 16(e)(1)(A) & (B). In considering these statutory factors, the court's inquiry is necessarily a limited one, as the government is entitled to "broad discretion to settle with the defendant within the reaches of the public interest." *United States* v. *Microsoft Corp.*, 56 F.3d 1448, 1461 (D.C. Cir. 1995); *see generally United States* v. *SBC Commc'ns, Inc.*, 489 F. Supp. 2d 1 (D.D.C. 2007) (assessing public interest standard under the Tunney Act); *United States v, U.S. Airways Group, Inc.*, 38 F. Supp. 3d 69, 75 (D.D.C. 2014) (noting the court has broad discretion of the adequacy of the relief at issue); *United States* v. *InBev N.V./S.A.*, No. 08–1965 (JR), 2009–2 Trade Cas. (CCH) ¶ 76,736, 2009 U.S. Dist. LEXIS 84787, at *3, (D.D.C. Aug. 11, 2009) (noting that the court's review of a consent judgment is limited and only inquires "into whether the government's determination that the proposed remedies will cure the antitrust violations alleged in the complaint was reasonable, and whether the mechanism to enforce the final judgment are clear and manageable.").[3]

As the United States Court of Appeals for the District of Columbia Circuit has held, under the APPA a court considers, among other things, the relationship between the remedy secured and the specific allegations set forth in the government's complaint, whether the decree is sufficiently clear, whether enforcement mechanisms are sufficient, and whether the decree may positively harm third parties. *See Microsoft*, 56 F.3d at 1458–62. With respect to the adequacy of the relief secured by the decree, a court may not "engage in an unrestricted evaluation of what relief would best serve the public." *United States* v. *BNS, Inc.*, 858 F.2d 456, 462 (9th Cir. 1988) (quoting *United States* v. *Bechtel Corp.*, 648 F.2d 660, 666 (9th Cir. 1981)); *see also Microsoft*, 56 F.3d at 1460–62; *United States* v. *Alcoa, Inc.*, 152 F. Supp. 2d 37, 40 (D.D.C. 2001); *InBev*, 2009 U.S. Dist. LEXIS 84787, at *3. Courts have held that:

> [t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General. The court's role in protecting the public interest is one of insuring that the government has not breached its duty to the public in consenting to the decree. The court is required to determine not whether a particular decree is the one that will best serve society, but whether the settlement is "*within the reaches of the public interest.*" More elaborate requirements might undermine the effectiveness of antitrust enforcement by consent decree.

Bechtel, 648 F.2d at 666 (emphasis added) (citations omitted).[4] In determining whether a proposed settlement is in the public interest, a district court "must accord deference to the government's predictions about the efficacy of its remedies, and may not require that the remedies perfectly match the alleged violations." *SBC Commc'ns*, 489 F. Supp. 2d at 17; *see also U.S. Airways*, 38 F. Supp. 3d at 75 (noting that a court should not reject the proposed remedies because it believes others are preferable); *Microsoft*, 56 F.3d at 1461 (noting the need for courts to be "deferential to the government's predictions as to the effect of the proposed remedies"); *United States* v. *Archer-Daniels-Midland Co.*, 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (noting that the court should grant due respect to the United States' prediction as to the effect of proposed remedies, its perception of the market structure, and its views of the nature of the case).

Courts have greater flexibility in approving proposed consent decrees than in crafting their own decrees following a finding of liability in a litigated matter. "[A] proposed decree must be approved even if it falls short of the remedy the court would impose on its own, as long as it falls within the range of acceptability or is 'within the reaches of public interest.'" *United States* v. *Am. Tel. & Tel. Co.*, 552 F. Supp. 131, 151 (D.D.C. 1982) (citations omitted) (quoting *United States* v. *Gillette Co.*, 406 F. Supp. 713, 716 (D. Mass. 1975)), *aff'd sub nom. Maryland* v. *United States*, 460 U.S. 1001 (1983); *see also U.S. Airways*, 38 F. Supp. 3d at 76 (noting that room must be made for the government to grant concessions in the negotiation process for settlements (citing *Microsoft*, 56 F.3d at 1461)); *United States* v. *Alcan Aluminum Ltd.*, 605 F. Supp. 619, 622 (W.D. Ky. 1985) (approving the consent decree even though the court would have imposed a greater remedy). To meet this standard, the United States "need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms." *SBC Commc'ns*, 489 F. Supp. 2d at 17.

Moreover, the court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its Complaint, and does not authorize the court to "construct [its] own hypothetical case and then evaluate the decree against that case." *Microsoft*, 56 F.3d at 1459; *see also U.S. Airways*, 38 F. Supp. 3d at 75 (noting that the court must simply determine whether there is a factual foundation for the government's decisions such that its conclusions regarding the proposed settlements are reasonable); *InBev*, 2009 U.S. Dist. LEXIS 84787, at *20 ("the 'public interest' is not to be measured by comparing the violations alleged in the complaint against those the court believes could have, or even should have, been alleged"). Because the "court's authority to review the decree depends entirely on the government's exercising its prosecutorial discretion by bringing a case in the first place," it follows that "the court is only authorized to review the decree itself," and not to "effectively redraft the complaint" to inquire into other matters that the United States did not pursue. *Microsoft,* 56 F.3d at 1459–60. As this Court recently confirmed in *SBC Communications,* courts "cannot look beyond the complaint in making the public interest determination unless the complaint is drafted so narrowly as to make a mockery of judicial power." *SBC Commc'ns,* 489 F. Supp. 2d at 15.

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[3] The 2004 amendments substituted "shall" for "may" in directing relevant factors for court to consider and amended the list of factors to focus on competitive considerations and to address potentially ambiguous judgment terms. *Compare* 15 U.S.C. 16(e) (2004), *with* 15 U.S.C. 16(e)(1) (2006); *see also SBC Commc'ns*, 489 F. Supp. 2d at 11 (concluding that the 2004 amendments "effected minimal changes" to Tunney Act review).

[4] *Cf. BNS*, 858 F.2d at 464 (holding that the court's "ultimate authority under the [APPA] is limited to approving or disapproving the consent decree"); *United States* v. *Gillette Co.*, 406 F. Supp. 713, 716 (D. Mass. 1975) (noting that, in this way, the court is constrained to "look at the overall picture not hypercritically, nor with a microscope, but with an artist's reducing glass"). *See generally Microsoft*, 56 F.3d at 1461 (discussing whether "the remedies [obtained in the decree are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest'").

In its 2004 amendments, Congress made clear its intent to preserve the practical benefits of utilizing consent decrees in antitrust enforcement, adding the unambiguous instruction that "[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene." 15 U.S.C. 16(e)(2); *see also U.S. Airways,* 38 F. Supp. 3d at 76 (indicating that a court is not required to hold an evidentiary hearing or to permit intervenors as part of its review under the Tunney Act). The language wrote into the statute what Congress intended when it enacted the Tunney Act in 1974, as Senator Tunney explained: "[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process." 119 Cong. Rec. 24,598 (1973) (statement of Sen. Tunney). Rather, the procedure for the public interest determination is left to the discretion of the court, with the recognition that the court's "scope of review remains sharply proscribed by precedent and the nature of Tunney Act proceedings." *SBC Commc'ns,* 489 F. Supp. 2d at 11.[5] A court can make its public interest determination based on the competitive impact statement and response to public comments alone. *U.S. Airways,* 38 F. Supp. 3d at 76.

VIII. DETERMINATIVE DOCUMENTS

There are no determinative materials or documents within the meaning of the APPA that were considered by the United States in formulating the proposed Final Judgment.

Date: April 20, 2016

Respectfully Submitted,

Kenneth A. Libby
Special Attorney

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA c/o Department of Justice Washington, D.C. 20530, Plaintiff, v. LEN BLAVATNIK c/o Access Industries, 28 Kensington Church Street, 4th Floor, London, United Kingdom W8 4EP, Defendant.

CASE NO.: 1:15–cv–01631
JUDGE: Randolph D. Moss
FILED: 10/06/2015

FINAL JUDGMENT

Plaintiff, the United States of America, having commenced this action by filing its Complaint herein for violation of Section 7A of the Clayton Act, 15 U.S.C. 18a, commonly known as the Hart-Scott-Rodino Antitrust Improvements Act of 1976, and Plaintiff and Defendant Len Blavatnik, by their respective attorneys, having consented to the entry of this Final Judgment without trial or adjudication of any issue of fact or law herein, and without this Final Judgment constituting any evidence against or an admission by the Defendant with respect to any such issue:

Now, therefore, before the taking of any testimony and without trial or adjudication of any issue of fact or law herein, and upon the consent of the parties hereto, it is hereby Ordered, Adjudged, and Decreed as follows:

I.

The Court has jurisdiction of the subject matter of this action and of the Plaintiff and the Defendant. The Complaint states a claim upon which relief can be granted against the Defendant under Section 7A of the Clayton Act, 15 U.S.C. 18a.

II.

Judgment is hereby entered in this matter in favor of Plaintiff United States of America and against Defendant, and, pursuant to Section 7A(g)(1) of the Clayton Act, 15 U.S.C. 18a(g)(1), the Debt Collection Improvement Act of 1996, Pub. L. 104–134 § 31001(s) (amending the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. 2461), Federal Trade Commission Rule 1.98, 16 CFR 1.98, 61 FR 54549 (Oct. 21, 1996), and 74 FR 857 (Jan. 9, 2009), Defendant Len Blavatnik is hereby ordered to pay a civil penalty in the amount of six hundred fifty six thousand dollars ($656,000). Payment of the civil penalty ordered hereby shall be made by wire transfer of funds or cashier's check. If the payment is made by wire transfer, Defendant shall contact Janie Ingalls of the Antitrust Division's Antitrust Documents Group at (202) 514–2481 for instructions before making the transfer. If the payment is made by cashier's check, the check shall be made payable to the United States Department of Justice and delivered to:

Janie Ingalls
United States Department of Justice
Antitrust Division, Antitrust Documents Group
450 5th Street NW., Suite 1024
Washington, DC 20530

Defendant shall pay the full amount of the civil penalty within thirty (30) days of entry of this Final Judgment. In the event of a default or delay in payment, interest at the rate of eighteen (18) percent per annum shall accrue thereon from the date of the default or delay to the date of payment.

III.

Each party shall bear its own costs of this action.

IV.

Entry of this Final Judgment is in the public interest.

Dated: ____________________

____

United States District Judge

[FR Doc. 2016–09782 Filed 4–26–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act and the Resource Conservation and Recovery Act

On April 20, 2016, the Department of Justice and the State of California on behalf of the California Department of Toxic Substances Control and Toxic Substances Control Account ("DTSC") filed a complaint and lodged a proposed Consent Decree with the United States District Court for the Central District of California pertaining to environmental contamination at Operable Unit 2 ("OU2") of the Omega Chemical Corporation Superfund Site ("Site") in Los Angeles County, California. The complaint and proposed Consent Decree were filed contemporaneously in the matter of *United States of America and State of California on behalf of the Department of Toxic Substances Control*

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[5] *See United States* v. *Enova Corp.,* 107 F. Supp. 2d 10, 17 (D.D.C. 2000) (noting that the "Tunney Act expressly allows the court to make its public interest determination on the basis of the competitive impact statement and response to comments alone"); *United States* v. *Mid-Am. Dairymen, Inc.,* No. 73–CV–681–W–1, 1977–1 Trade Cas. (CCH) ¶ 61,508, at 71,980, *22 (W.D. Mo. 1977) ("Absent a showing of corrupt failure of the government to discharge its duty, the Court, in making its public interest finding, should . . . carefully consider the explanations of the government in the competitive impact statement and its responses to comments in order to determine whether those explanations are reasonable under the circumstances."); S. Rep. No. 93–298, at 6 (1973) ("Where the public interest can be meaningfully evaluated simply on the basis of briefs and oral arguments, that is the approach that should be utilized.").

and Toxic Substances Control Account v. *Abex Aerospace et al.*, Civil Action No. 2:16–cv–02696 (C.D. Cal.).

The proposed Consent Decree resolves certain claims under Sections 106 and 107 of the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9606, 9607 and Section 7003 of the Resource Conservation and Recovery Act, 42 U.S.C. 6973, as well as related state law claims, in connection with environmental contamination at OU2. The Consent Decree requires the settling defendants, which include as Settling Work Defendants the members of the Omega PRP Organized Group ("OPOG") and McKesson Corporation, and also include various Settling Cash Defendants, to perform work at OU2 and to make a payment of $8 million toward the United States' unreimbursed OU2 past costs, and a payment of $70,000 towards DTSC's unreimbursed OU2 past costs. The proposed Consent Decree also requires the settling defendants to pay the United States' and DTSC's future response costs for overseeing the work the settling defendants will be performing at OU2.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States of America and State of California on behalf of the Department of Toxic Substances Control and Toxic Substances Control Account* v. *Abex Aerospace et al.*, D.J. Ref. No. 90–11–3–06529/10. A hearing will be held on the proposed settlement if requested in writing within the public comment period. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department Web site: *https://www.usdoj.gov/enrd/consent-decrees.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $86.50 (25 cents per page reproduction cost) for the Consent Decree, payable to the United States Treasury. For a paper copy without the exhibits and signature pages, the cost is $22.75.

Henry S. Friedman,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2016–09864 Filed 4–26–16; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (OJJDP) Docket No. 1710]

Webinar Meeting of the Federal Advisory Committee on Juvenile Justice

AGENCY: Office of Juvenile Justice and Delinquency Prevention, Justice.

ACTION: Notice of webinar meeting.

SUMMARY: The Office of Juvenile Justice and Delinquency Prevention (OJJDP) has scheduled a webinar meeting of the Federal Advisory Committee on Juvenile Justice (FACJJ).

DATES: The webinar meeting will take place online on Wednesday May 18, 2016 at 2:00 p.m. EDT.

FOR FURTHER INFORMATION CONTACT: Jeff Slowikowski, Designated Federal Official, OJJDP, *Jeff.Slowikowski@usdoj.gov*, or (202) 616–3646. [This is not a toll-free number.]

SUPPLEMENTARY INFORMATION: FACJJ, established pursuant to Section 3(2)A of the Federal Advisory Committee Act (5 U.S.C. App.2), will meet to carry out its advisory functions under Section 223(f)(2)(C–E) of the Juvenile Justice and Delinquency Prevention Act of 2002. The FACJJ is composed of representatives from the states and territories. FACJJ member duties include: Reviewing Federal policies regarding juvenile justice and delinquency prevention; advising the OJJDP Administrator with respect to particular functions and aspects of OJJDP; and advising the President and Congress with regard to State perspectives on the operation of OJJDP and Federal legislation pertaining to juvenile justice and delinquency prevention. More information on the FACJJ may be found at *www.facjj.org*.

Meeting Agenda: The proposed agenda includes: (a) Opening Introductions, and Webinar Logistics; (b) Remarks of Robert L. Listenbee, Administrator, OJJDP; (c) FACJJ Subcommittee Reports (Legislation; Expungement/Sealing of Juvenile Court Records; Research/Publications)); (d) FACJJ Administrative Business; and (e) Summary, Next Steps, and Meeting Adjournment.

To participate in or view the webinar meeting, FACJJ members and the public must pre-register online. Members and interested persons must link to the webinar registration portal through *www.facjj.org*, no later than Monday, May 16, 2016. Upon registration, information will be sent to you at the email address you provide to enable you to connect to the webinar. Should problems arise with webinar registration, please call Callie Long Murray at 571–308–6617. [This is not a toll-free telephone number.] Note: Members of the public will be able to listen to and view the webinar as observers, but will not be able to participate actively in the webinar.

An on-site room is available for members of the public interested in viewing the webinar in person. If members of the public wish to view the webinar in person, they must notify Melissa Kanaya by email message at *mkanaya@aeioonline.com* no later than Friday, May 13, 2016.

FACJJ members will not be physically present in Washington, DC for the webinar. They will participate in the webinar from their respective home jurisdictions.

Written Comments: Interested parties may submit written comments by email message in advance of the webinar to Jeff Slowikowski, Designated Federal Official, at *Jeff.Slowikowski@usdoj.gov*, no later than Monday, May 16, 2016. In the alternative, interested parties may fax comments to 202–307–2819 and contact Yasmeen Hines at 202–598–9785 to ensure that they are received. [These are not toll-free numbers.]

Robert L. Listenbee,

Administrator, Office of Juvenile Justice and Delinquency Prevention.

[FR Doc. 2016–09756 Filed 4–26–16; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (OJJDP) Docket No. 1707]

Meeting of the Coordinating Council on Juvenile Justice and Delinquency Prevention

AGENCY: Coordinating Council on Juvenile Justice and Delinquency Prevention, Justice.

ACTION: Notice of meeting.

SUMMARY: The Coordinating Council on Juvenile Justice and Delinquency Prevention ("Council") announces its next meeting.

DATES: Friday, June 17, 2016 from 10:00 a.m. to 12:00 p.m. (Eastern Time).

ADDRESSES: The meeting will take place in the third floor main conference room at the U.S. Department of Justice, Office of Justice Programs, 810 7th St. NW., Washington, DC 20531.

FOR FURTHER INFORMATION CONTACT: Visit the Web site for the Coordinating Council at *www.juvenilecouncil.gov* or contact Jeff Slowikowski, Designated Federal Official (DFO), OJJDP, by telephone at (202) 616–3646 (not a toll-free number) or via email: *jeff.slowikowski@usdoj.gov.* The meeting is open to the public.

SUPPLEMENTARY INFORMATION: The Council, established by statute in the Juvenile Justice and Delinquency Prevention Act of 1974 (42 U.S.C. 5616(a)), will meet to carry out its advisory functions. Documents such as meeting announcements, agendas, minutes, and reports will be available on the Council's Web page, *www.juvenilecouncil.gov* where you may also obtain information on the meeting.

Although designated agency representatives may attend, the Council membership consists of the Attorney General (Chair), the Administrator of the Office of Juvenile Justice and Delinquency Prevention (Vice Chair), the Secretary of Health and Human Services (HHS), the Secretary of Labor (DOL), the Secretary of Education (DOE), the Secretary of Housing and Urban Development (HUD), the Director of the Office of National Drug Control Policy, the Chief Executive Officer of the Corporation for National and Community Service, and the Assistant Secretary of Homeland Security for U.S. Immigration and Customs Enforcement. The nine additional members are appointed by the Speaker of the U.S. House of Representatives, the U.S. Senate Majority Leader, and the President of the United States. Other federal agencies take part in Council activities, including the Departments of Agriculture, Defense, Interior, and the Substance and Mental Health Services Administration of HHS.

Meeting Agenda: The agenda will include: (a) Opening remarks and introductions; (b) Discussion of the Overview of National, State and Local Efforts to Reduce and Prevent Youth Violence; and (c) Council member announcements.

Registration: For security purposes, members of the public who wish to attend the meeting must pre-register online at *www.juvenilecouncil.gov* no later than Tuesday, June 14, 2016. Should problems arise with web registration, contact Melissa Kanaya, Senior Program Manager/Federal Contractor, at (202) 280–8874 or (202) 514–9373 or send a request to register to Ms. Kanaya. Please include name, title, organization or other affiliation, full address and phone, fax and email information and send to her attention either by fax to (866) 854–6619, or by email to *mkanaya@aeioonline.com.* Note that these are not toll-free telephone numbers. Additional identification documents may be required. Meeting space is limited.

Note: Photo identification will be required for admission to the meeting.

Written Comments: Interested parties may submit written comments and questions in advance by Tuesday, June 14, 2016, to Mr. Slowikowski, at *jeff.slowikowski@usdoj.gov.* Alternatively, fax your comments to (866) 854–6619 and contact Ms. Kanaya at (202) 280–8874 or (202) 514–9373 to ensure that they are received.

The Council expects that the public statements submitted will not repeat previously submitted statements. Written questions from the public are also invited at the meeting.

Robert L. Listenbee,

Administrator, Office of Juvenile Justice and Delinquency Prevention.

[FR Doc. 2016–09755 Filed 4–26–16; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

Agency Information Collection Activities; Announcement of OMB Approvals

AGENCY: Employee Benefits Security Administration, Department of Labor.

ACTION: Notice.

SUMMARY: The Employee Benefits Security Administration (EBSA) announces that the Office of Management and Budget (OMB) has approved certain collections of information, listed in the **SUPPLEMENTARY INFORMATION** below, following EBSA's submission of requests for such approvals under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*). This notice describes the information collections that have been approved or re-approved, their OMB control numbers, and their current expiration dates.

FOR FURTHER INFORMATION CONTACT: G. Christopher Cosby, Office of Policy and Research, Employee Benefits Security Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–5718, Washington, DC 20210. Telephone: (202) 693–8410; Fax: (202) 219–4745. These are not toll-free numbers.

SUPPLEMENTARY INFORMATION: The PRA and its implementing regulations require Federal agencies to display OMB control numbers and inform respondents of their legal significance after OMB has approved an agency's information collections. In accordance with those requirements, EBSA hereby notifies the public that the following information collections have been re-approved by OMB following EBSA's submission of an information collection request (ICR) for extension of a prior approval:

- OMB Control No. 1210–0059, Employee Retirement Income Security Act Prohibited Transaction Exemption 1986–128 For Securities Transactions Involving Employee Benefit Plans and Broker-Dealers. The expiration date for this information collection is March 31, 2018.
- OMB Control No. 1210–0066, Employee Retirement Income Security Act Procedure 1976–1; Advisory Opinion Procedure. The expiration date for this information collection is August 31, 2018.
- OMB Control No. 1210–0083, PTE 1990–1; Insurance Company Pooled Separate Accounts. The expiration date for this information collection is December 31, 2018.
- OMB Control No. 1210–0084, Employee Retirement Income Security Act of 1974 Technical Release 91–1. The expiration date for this information collection is August 31, 2018.
- OMB Control No. 1210–0091, Settlement Agreements Between a Plan and a Party in Interest. The expiration date for this information collection is December 31, 2018.
- OMB Control No. 1210–0110, Annual Information Return/Report of Employee Benefit Plan. The expiration date for this information collection is August 31, 2018.
- OMB Control No. 1210–0112, Furnishing Documents to the Secretary of Labor on Request Under ERISA Section 104(a)(6). The expiration date for this information collection is April 30, 2018.
- OMB Control No. 1210–0114, Disclosures by Insurers to General

Account Policyholders. The expiration date for this information collection is August 31, 2018.

- OMB Control No. 1210–0115, Prohibited Transaction Class Exemption for Cross-Trades of Securities by Index and Model-Driven Funds (PTCE 2002–12). The expiration date for this information collection is December 31, 2018.
- OMB Control No. 1210–0117, Registration for EFAST–2 Credentials. The expiration date for this information collection is September 30, 2018.
- OMB Control No. 1210–0118, Voluntary Fiduciary Correction Program. The expiration date for this information collection is December 31, 2018.
- OMB Control No. 1210–0121, Consent to Receive Employee Benefit Plan Disclosures Electronically. The expiration date for this information collection is March 31, 2018.
- OMB Control No. 1210–0122, Employee Retirement Income Security Act Blackout Period Notice. The expiration date for this information collection is August 31, 2018.
- OMB Control No. 1210–0124, Acquisition and Sale of Trust Real Estate Investment Trust Shares by Individual Account Plans Sponsored by Trust Real Estate Investment Trusts. The expiration date for this information collection is December 31, 2018.
- OMB Control No. 1210–0127, Abandoned Individual Account Plan Termination. The expiration date for this information collection is December 31, 2018.
- OMB Control No. 1210–0133, Employee Retirement Income Security Act Section 408(b)(2) Regulation. The expiration date for this information collection is May 31, 2018.
- OMB Control No. 1210–0144, Affordable Care Act Internal Claims and Appeals and External Review Procedures for Non-Grandfathered Plans. The expiration date for this information collection is March 31, 2019.
- OMB Control No. 1210–0147, Affordable Care Act Section 2715 Summary Disclosures. The expiration date for this information collection is April 30, 2019.

EBSA hereby notifies the public that the following information collections have been approved by OMB following EBSA's submission of an information collection request (ICR) for a revision of a currently approved collection:

- OMB Control No. 1210–0126, Annual Funding Notice for Defined Benefit Pension Plans. The expiration date for this information collection is April 30, 2018.
- OMB Control No. 1210–0150, Coverage of Certain Preventive Services Under the Affordable Care Act. The expiration date for this information collection is September 30, 2018.

EBSA hereby notifies the public that the following new information collections have been approved by OMB following EBSA's submission of an information collection request (ICR):

- OMB Control No. 1210–0152, Coverage of Certain Preventive Services Under the Affordable Care Act—For-Profit Entities. The expiration date for this information collection is September 30, 2018.
- OMB Control No. 1210–0154, Focus Groups for Evaluating the Effectiveness of Employee Retirement Income Security Act Section 408(b)(2) Disclosure Requirements. The expiration date for this information collection is January 31, 2018.

The PRA provides that an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Publication of this notice satisfies this requirement with respect to the above-listed information collections, as provided in 5 CFR 1320.5(b)(2)(C).

Joseph S. Piacentini,

Director, Office of Policy and Research, Employee Benefits Security Administration.

[FR Doc. 2016–09713 Filed 4–26–16; 8:45 am]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; ETA Workforce Innovation and Opportunity Act Performance Accountability, Information, and Reporting System

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Employment and Training Administration sponsored information collection request (ICR) proposal titled, "ETA Workforce Innovation and Opportunity Act Performance Accountability, Information, and Reporting System," to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 *et seq.*). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before May 27, 2016.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201604-1205-003* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–ETA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor—OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks PRA authority for the ETA Workforce Innovation and Opportunity Act (WIOA) Performance Accountability, Information, and Reporting System information collection. The following programs will be required to report through this system: WIOA Adult, Dislocated Worker and Youth, Wagner Peyser Employment Service, National Farmworker Jobs, Trade Adjustment Assistance, YouthBuild, Indian and Native American, Job Corps, and Jobs for Veterans' State Grants. Requiring these programs to use a standard set of data elements, definitions, and specifications at all levels of the workforce system helps improve the quality of the performance information that is received by the DOL. While H1–B grants, the Reintegration of Ex-Offenders program, and the Trade Adjustment Assistance program are not authorized under the WIOA, these programs will be utilizing the data element definitions and reporting templates proposed in this ICR. The accuracy, reliability, and comparability of program reports submitted by states and grantees using Federal funds are fundamental elements of good public administration, and are necessary tools for maintaining and demonstrating system integrity. This ICR includes several information collection instruments—Program Performance Report, WIOA Pay-for-Performance Report, Participant Individual Record Layout, WIOA Data Element Specifications, and Job Openings Report. WIOA section 185 authorizes this information collection. *See* 29 U.S.C. 3245.

This proposed information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information if the collection of information does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. For additional information, see the related notices published in the **Federal Register** on April 16, 2015 (80 FR 20573), and September 1, 2015 (80 FR 52798).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB ICR Reference Number 201604–1205–003. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Agency: DOL–ETA.

Title of Collection: ETA Workforce Innovation and Opportunity Act Performance Accountability, Information, and Reporting System.

OMB ICR Reference Number: 201604–1205–003.

Affected Public: State, Local, and Tribal Governments; Private Sector.

Total Estimated Number of Respondents: 1,801.

Total Estimated Number of Responses: 17,261,469.

Total Estimated Annual Time Burden: 4,471,044 hours.

Total Estimated Annual Other Costs Burden: $6,791,395.

Dated: April 21, 2016.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2016–09807 Filed 4–26–16; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Occupational Safety and Health State Plans

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting Occupational Safety and Health Administration (OSHA) sponsored information collection request (ICR) titled, "Occupational Safety and Health State Plans," to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.* Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before May 27, 2016.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=20201601-1218-001* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OSHA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Occupational Safety and Health State Plans information collection. Occupational Safety and Health Act of 1970 section 18 encourages States to assume responsibility for the development and enforcement of State occupational safety and health standards through the mechanism of an approved State plan. Absent a plan approved by the OSHA, a State is preempted from asserting authority over any occupational safety and health issue with respect to which a Federal standard has been promulgated. Section 18 establishes the basic criteria for State plan approval; provides for the discretionary exercise of concurrent Federal enforcement jurisdiction for a period of time following initial approval; provides that State standards and enforcement must be, and continue to be, at least as effective as the Federal program, including any change thereto; and requires the OSHA to make a continuing evaluation of the State plan to take action to withdraw plan approval should there be a failure to substantially comply with any provision of the State Plan. A State choosing to operate an OSHA-approved plan must provide information to document the State program is at least as effective as the Federal OSHA program. In order to obtain and maintain State Plan approval, a State must submit various documents to the OSHA describing the Plan program structure and operation, including any modification thereto as it occurs, in accordance with the identified regulations.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1218–0247.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on April 30, 2016. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on January 27, 2016 (81 FR 4672).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1218–0247.

The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–OSHA.

Title of Collection: Occupational Safety and Health State Plans.

OMB Control Number: 1218–0247.

Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Respondents: 28.

Total Estimated Number of Responses: 1,309.

Total Estimated Annual Time Burden: 11,519 hours.

Total Estimated Annual Other Costs Burden: $0.

Dated: April 21, 2016.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2016–09751 Filed 4–26–16; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petitions for Modification of Application of Existing Mandatory Safety Standards

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice.

SUMMARY: Section 101(c) of the Federal Mine Safety and Health Act of 1977 and Title 30 of the Code of Federal Regulations Part 44 govern the application, processing, and disposition of petitions for modification. This notice is a summary of petitions for modification submitted to the Mine Safety and Health Administration (MSHA) by the parties listed below.

DATES: All comments on the petitions must be received by the MSHA's Office of Standards, Regulations, and Variances on or before May 27, 2016.

ADDRESSES: You may submit your comments, identified by "docket number" on the subject line, by any of the following methods:

1. *Electronic Mail: zzMSHA-comments@dol.gov.* Include the docket number of the petition in the subject line of the message.
2. *Facsimile:* 202–693–9441.
3. *Regular Mail or Hand Delivery:* MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202–5452, Attention: Sheila McConnell, Director, Office of Standards, Regulations, and Variances. Persons delivering documents are required to check in at the receptionist's desk in Suite 4E401. Individuals may inspect copies of the petitions and comments during normal business hours at the address listed above.

MSHA will consider only comments postmarked by the U.S. Postal Service or proof of delivery from another delivery service such as UPS or Federal Express on or before the deadline for comments.

FOR FURTHER INFORMATION CONTACT: Barbara Barron, Office of Standards, Regulations, and Variances at 202–693–9447 (Voice), *barron.barbara@dol.gov* (Email), or 202–693–9441 (Facsimile). [These are not toll-free numbers.]

SUPPLEMENTARY INFORMATION:

I. Background

Section 101(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act) allows the mine operator or representative of miners to file a petition to modify the application of any mandatory safety standard to a coal or other mine if the Secretary of Labor determines that:

1. An alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard; or
2. That the application of such standard to such mine will result in a diminution of safety to the miners in such mine.

In addition, the regulations at 30 CFR 44.10 and 44.11 establish the requirements and procedures for filing petitions for modification.

II. Petitions for Modification

Docket Number: M–2016–001–M.

Petitioner: The Doe Run Company, Three Gateway Center, Suite 1500, 401 Liberty Avenue, Pittsburgh, Pennsylvania 15222–1000.

Mines: Buick Mine/Mill, MSHA I.D. No. 23–00457 and Viburnum No. 35 (Casteel Mine), MSHA I.D. No. 23–01800, located in Iron County, Missouri; Sweetwater Mine/Mill, MSHA I.D. No. 23–00458, Fletcher Mine/Mill, MSHA I.D. No. 23–00409, and Brushy Creek Mine/Mill, MSHA I.D. No. 23–00499, located in Reynolds County, Missouri; and Viburnum No. 29 Mine, MSHA I.D. No. 23–00495, located in Washington County, Missouri.

Regulation Affected: 30 CFR 57.11050 (Escapeways and refuges).

Modification Request: The petitioner requests a modification of the existing standard to permit an alternative method of compliance with respect to escapeways. The petitioner states that:

(1) The Doe Run Company operates six underground lead mines near Viburnum, Missouri. The Buick Mine is

currently considered "inactive" by MSHA but mining is occurring within the boundaries of the mine. The mines consist of both development and production headings. Activities include drilling, blasting, scaling, loading, and hauling of ore.

(2) All of Doe Run's mines access the elevation where the ore bodies are located by means of shafts. The ore body is accessed horizontally from such shafts. Each mine has two escapeways from what would be considered the lowest levels of each mine.

(3) Provision of two escapeways from each working area will be difficult, burdensome and unnecessarily costly. It will involve, in part, mining areas where there is no ore present and it will consume extensive periods of time. There are numerous areas at issue and abatement may involve millions of dollars of expense in certain areas.

(4) As an alternative to compliance to the existing standard 30 CFR 57.11050, the petitioner proposes the following:

(a) All active mining headings or development headings with more than 1000 feet of single access drift in the roadway leading to it will have a Designated Point of Safety (DPOS) within 1000 feet of every working heading.

(b) In cases where the mining area opens up to multiple drifts inby the 1000 feet of single access, the DPOS will be placed inby the last point of single access but not necessarily within 1000 feet of all working faces.

(c) Portable escape hoist vent shafts and roadways to other mines "inby" the 1000 feet of single access will eliminate the need for a DPOS.

(d) The DPOS for each work area that does not have two escapeways from the work area will comply with requirements for refuge alternatives in 30 CFR part 7, specifically as follows:

(i) Prefabricated self-contained units, including the structural breathable air, air monitoring, and harmful gas removal components of the unit will be approved under 30 CFR part 7.

(ii) Refuge alternatives will provide at least 15 square feet of floor space per person and 30 to 60 cubic feet of volume per person. The airlock can be included in the space and volume if waste is disposed outside the refuge alternative.

(iii) The operator will protect the refuge alternative and contents from damage during transportation, installation, and storage.

(iv) A refuge alternative will be removed from service if examination reveals damage that interferes with the functioning of the refuge alternative or any component.

(a) If a refuge alternative is removed from service, the operator will withdraw all persons from the area serviced by the refuge alternative, except those persons referred to in § 104(c) of the Mine Act.

(b) Refuge alternative components removed from service will be replaced or be repaired for return to service in accordance with the manufacturer's specifications.

(v) At all times, the site and area around the refuge alternative will be kept clear of machinery, materials, and obstructions that could interfere with the deployment or use of the refuge alternative.

(vi) Each refuge alternative will be conspicuously identified with a sign or marker as follows:

(a) A sign or marker made of a reflective material with the word "Refuge" will be posted conspicuously at each refuge alternative.

(b) Directional signs made of a reflective material will be posted leading to each refuge alternative location.

(vii) During the use of the refuge alternative, the atmosphere within the refuge alternative will be monitored. Changers or adjustments will be made to reduce the concentration of carbon dioxide to 1 percent or less and excursions not exceeding 2.5 percent; and to reduce the concentration of carbon monoxide to 25 ppm or less. Oxygen will be maintained at 18.5 to 23 percent.

(viii) Refuge alternatives will contain a fire extinguisher that:

(a) Meets the requirements for portable fire extinguishers used in underground coal mines under this part;

(b) Is appropriate for extinguishing fires involving the chemical used for harmful gas removal; and

(c) Uses of low-toxicity extinguishing agent that does not produce a hazardous by-product when activated.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded by the existing standard.

Sheila McConnell,

Director, Office of Standards, Regulations, and Variances.

[FR Doc. 2016–09797 Filed 4–26–16; 8:45 am]

BILLING CODE 4520–43–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petitions for Modification of Application of Existing Mandatory Safety Standards

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice.

SUMMARY: Section 101(c) of the Federal Mine Safety and Health Act of 1977 and Title 30 of the Code of Federal Regulations Part 44 govern the application, processing, and disposition of petitions for modification. This notice is a summary of petitions for modification submitted to the Mine Safety and Health Administration (MSHA) by the parties listed below.

DATES: All comments on the petitions must be received by the MSHA's Office of Standards, Regulations, and Variances on or before May 27, 2016.

ADDRESSES: You may submit your comments, identified by "docket number" on the subject line, by any of the following methods:

1. *Electronic Mail: zzMSHA-comments@dol.gov.* Include the docket number of the petition in the subject line of the message.

2. *Facsimile:* 202–693–9441.

3. *Regular Mail or Hand Delivery:* MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202–5452, Attention: Sheila McConnell, Director, Office of Standards, Regulations, and Variances. Persons delivering documents are required to check in at the receptionist's desk in Suite 4E401. Individuals may inspect copies of the petitions and comments during normal business hours at the address listed above.

MSHA will consider only comments postmarked by the U.S. Postal Service or proof of delivery from another delivery service such as UPS or Federal Express on or before the deadline for comments.

FOR FURTHER INFORMATION CONTACT: Barbara Barron, Office of Standards, Regulations, and Variances at 202–693–9447 (Voice), *barron.barbara@dol.gov* (Email), or 202–693–9441 (Facsimile). [These are not toll-free numbers.]

SUPPLEMENTARY INFORMATION:

I. Background

Section 101(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act) allows the mine operator or representative of miners to file a petition to modify the application of any mandatory safety standard to a coal or other mine if the Secretary of Labor determines that:

1. An alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard; or

2. That the application of such standard to such mine will result in a diminution of safety to the miners in such mine.

In addition, the regulations at 30 CFR 44.10 and 44.11 establish the requirements and procedures for filing petitions for modification.

II. Petitions for Modification

Docket Number: M–2016–010–C.

Petitioner: Buckingham Coal Company, P.O. Box 400, Corning, Ohio 43730–0400.

Mine: Buckingham Mine #6, MSHA I.D. No. 33–04526, located in Perry County, Ohio.

Regulation Affected: 30 CFR 75.1101–1(b) (Deluge-type water spray systems).

Modification Request: The petitioner requests a modification of the existing standard to allow the mine not to provide blow-off dust covers on deluge-type system nozzles under existing 30 CFR 75.1101–1(b). The functional tests required of the deluge system each year will instead be done weekly. The petitioner states that the #6 Mine maintains more than adequate pressure and flow rates for the deluge system, and in some tests, the dust covers do not come off all sprays. The petitioner further states that:

(1) By doing the functional test weekly, all sprays can be inspected and maintained on a weekly basis.

(2) The dust covers provide protection for sprays which are tested yearly and by testing weekly the covers are not necessary.

The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure or protection afforded by the existing standard.

Sheila McConnell,

Director, Office of Standards, Regulations, and Variances.

[FR Doc. 2016–09798 Filed 4–26–16; 8:45 am]

BILLING CODE 4520–43–P

LIBRARY OF CONGRESS

U.S. Copyright Office

[Docket No. 2015–7]

Section 512 Study: Notice of Location Change for California Public Roundtables

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Notice of location change for California public roundtables.

SUMMARY: The United States Copyright Office has changed the location of the May 12 and 13, 2016 public roundtables on the section 512 study. The Office announced the public roundtables in New York and California by notice in the **Federal Register** on March 18, 2016. *See* 81 FR 14896. The May 12 and 13, 2016 public roundtables in California will now be held in Courtroom 4 of the Ninth Circuit James R. Browning Courthouse, 95 Seventh Street, San Francisco, California 94103.

Dates and Addresses

The California roundtable will take place on May 12 and 13, 2016, from 9:00 a.m. to 5:00 p.m. on both days, and will be held in Courtroom 4 of the Ninth Circuit James R. Browning Courthouse, 95 Seventh Street, San Francisco, California 94103.

FOR FURTHER INFORMATION CONTACT: Jacqueline C. Charlesworth, General Counsel and Associate Register of Copyrights, *jcharlesworth@loc.gov;* or Karyn Temple Claggett, Director of the Office of Policy and International Affairs and Associate Register of Copyrights, *kacl@loc.gov.* Both can be reached by telephone at 202–707–8350.

SUPPLEMENTARY INFORMATION: On December 31, 2015, the Copyright Office issued a Notice of Inquiry seeking public comment on thirty topics concerning the efficiency and effectiveness of section 512 of Title 17. *See* 80 FR 81862. The Office then issued a notice of public roundtables on March 18, 2016 announcing two two-day public roundtables on section 512 to be held in New York, New York on May 2 and 3, 2016, and Stanford, California on May 12 and 13, 2016. *See* 81 FR 14896. Interested members of the public were directed to submit participation requests through forms posted on the Office's Web site no later than April 11, 2016.

Due to the significant level of interest in the proceeding, the Office has decided to move the location of the California roundtable to Courtroom 4 of the Ninth Circuit James R. Browning Courthouse, 95 Seventh Street, San Francisco, California 94103.

Please note that the roundtable hearing rooms, in New York and California, will have a limited number of seats for participants and observers. For individuals who wish to observe a roundtable, the Office will provide public seating on a first-come, first-served basis on the days of the roundtables.

Individuals selected for participation in one or more of the roundtable sessions have been notified directly by the Office. For additional information about the specific topics to be covered at the roundtables, please see *http://copyright.gov/policy/section512/public-roundtable/participate-request.html.*

Dated: April 22, 2016.

Jacqueline C. Charlesworth,

General Counsel and Associate Register of Copyrights, U.S. Copyright Office.

[FR Doc. 2016–09869 Filed 4–26–16; 8:45 am]

BILLING CODE 1410–30–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: 16–030]

Aerospace Safety Advisory Panel; Meeting

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration announces a forthcoming meeting of the Aerospace Safety Advisory Panel.

DATES: Thursday, May 12, 2016, 10:30 a.m. to 11:45 a.m., Central Time.

ADDRESSES: NASA Marshall Space Flight Center, Building 4200, Room 600, Huntsville, Alabama 35812.

FOR FURTHER INFORMATION CONTACT: Ms. Marian Norris, Aerospace Safety Advisory Panel Administrative Officer, NASA Headquarters, Washington, DC 20546, (202) 358–4452 or *mnorris@nasa.gov.*

SUPPLEMENTARY INFORMATION: The Aerospace Safety Advisory Panel (ASAP) will hold its Second Quarterly Meeting for 2016. This discussion is pursuant to carrying out its statutory duties for which the Panel reviews, identifies, evaluates, and advises on those program activities, systems, procedures, and management activities that can contribute to program risk. Priority is given to those programs that involve the safety of human flight. The agenda will include:

—Updates on the Exploration Systems Development
—Updates on the Commercial Crew Program
— Updates on the International Space Station Program

The meeting will be open to the public up to the seating capacity of the room. Seating will be on a first-come basis. This meeting is also available telephonically. Any interested person may call the USA toll free conference call number (800) 857–7040; pass code 2708980. Attendees will be required to sign a visitor's register and to comply with NASA Marshall Space Flight Center security requirements, including the presentation of a valid picture ID and a secondary form of ID, before receiving an access badge. Due to the Real ID Act, Public Law 109–13, any attendees with drivers licenses issued from noncompliant states/territories must present a second form of ID. Noncompliant states/territories are American Samoa, Illinois, Minnesota, Missouri, New Mexico, and Washington. All U.S. citizens desiring to attend the Aerospace Safety Advisory Panel meeting at the Marshall Space Flight Center must provide their full name, company affiliation (if applicable), driver's license number and state, citizenship, place of birth, and date of birth to the Marshall Space Flight Center Protective Services and Export Control Office no later than close of business on May 9, 2016. All non-U.S. citizens must submit their name; current address; driver's license number and state (if applicable); citizenship; company affiliation (if applicable) to include address, telephone number, and title; place of birth; date of birth; U.S. visa information to include type, number, and expiration date; U.S. Social Security Number (if applicable); Permanent Residents (green card holders) number and expiration date (if applicable); place and date of entry into the U.S.; and Passport information to include Country of issue, number, and expiration date to the Marshall Space Flight Center Protective Services and Export Control Office no later than close of business on May 4, 2016. If the above information is not received by the noted dates, attendees should expect a minimum delay of four (4) hours. All visitors to this meeting will be required to process in through the Redstone/Marshall Space Flight Center Joint Visitor Control Center located on Rideout Road, north of Gate 9, prior to entering Marshall Space Flight Center. Please provide the appropriate data, via fax at (256) 544–2101, noting at the top of the page "Public Admission to the ASAP Meeting at MSFC." For security questions, please call Becky Hopson at (256) 544–4541. At the beginning of the meeting, members of the public may make a verbal presentation to the Panel on the subject of safety in NASA, not to exceed 5 minutes in length. To do so, members of the public must contact Ms. Marian Norris at *mnorris@nasa.gov* or at (202) 358–4452 at least 48 hours in advance. Any member of the public is permitted to file a written statement with the Panel at the time of the meeting. Verbal presentations and written comments should be limited to the subject of safety in NASA. It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

Patricia D. Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2016–09802 Filed 4–26–16; 8:45 am]

BILLING CODE 7510–13–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0088]

Draft Standard Review Plan on Foreign Ownership, Control, or Domination, Revision 1

AGENCY: Nuclear Regulatory Commission.

ACTION: Standard review plan-draft section revision; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is soliciting public comment on the Draft Standard Review Plan on Foreign Ownership, Control, or Domination, Revision 1. The Standard Review Plan (SRP) provides guidance and establishes procedures for NRC staff to review the issue of whether an applicant for a nuclear facility license is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government. This SRP will be used as the basis for such reviews in connection with license applications for new facilities, or applications for approval of direct or indirect transfers of facility licenses.

DATES: Comments must be filed no later than May 27, 2016. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0088. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Shawn W. Harwell, Office of Nuclear Reactor Regulation, telephone: 301–415–1309; email: *Shawn.Harwell@nrc.gov,* U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2016–0088 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0088.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "*ADAMS Public Documents*" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The Draft Standard Review Plan on Foreign Ownership, Control, or Domination, Revision 1, is available in ADAMS under Accession No. ML16048A025.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2016–0088 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Discussion

The NRC is issuing this revision to the SRP on Foreign Ownership, Control, or Domination (FOCD), to provide guidance and establish procedures for NRC staff's review of whether an applicant for a nuclear facility license issued under sections 103.d., "Commercial Licenses," or 104.d., "Medical Therapy and Research and Development," of the Atomic Energy Act of 1954, as amended (AEA or Act), is owned, controlled, or dominated by an alien, a foreign corporation, or a foreign government (individually or collectively, a foreign entity). Specifically, this revision of the SRP establishes guidance on graded negation action plan (NAP) criteria; provides for the consideration of site-specific criteria, as necessary; allows for the use of license conditions to incorporate NAPs and the staff's "totality of facts" review approach; and incorporates provisions for analyzing foreign financing. This SRP will be used as the basis for the conduct of FOCD reviews associated with license applications for new facilities to be licensed under title 10 of the *Code of Federal Regulations* (10 CFR), parts 50 and 52; applications for the renewal of facility licenses; or applications for approval of direct or indirect transfers of facility licenses.

Where there are co-applicants, each intending to own an interest in a new facility as co-licensees, the reviewer should consider each applicant to determine whether it is owned, controlled, or dominated by a foreign entity. If a co-licensee of an existing facility owns a partial interest in the facility and is transferring that interest, the acquirer should also be considered to determine whether it is owned, controlled, or dominated by a foreign entity.

The FOCD determination is to be made with an orientation toward the common defense and security. The provisions in the AEA for FOCD and inimicality, and the staff's reviews of these areas under NRC regulations, are derived from the same national security concerns, but appear in separate and distinct language in the AEA. The FOCD provisions in the AEA and NRC regulations are country-neutral, whereas the staff's inimicality review and its findings directly account for a license applicant's country of origin and any ties or interests that could result in a determination of inimicality. As such, while FOCD and inimicality are closely related, this SRP does not address the determination of whether issuance of a license would be inimical to the common defense and security or to the health and safety of the public.

The previous revision of this SRP was approved by the Commission in its staff requirements memorandum on SECY–99–165, "Final Standard Review Plan Regarding Foreign Ownership, Control, or Domination of Applicants for Reactor Licenses," dated August 31, 1999, and published in the **Federal Register** on September 28, 1999. Revision 1 to this SRP has been updated to reflect current NRC regulations and policy.

Dated at Rockville, Maryland, this 19th day of April 2016.

For the Nuclear Regulatory Commission.

William M. Dean,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. 2016–09916 Filed 4–26–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS) Meeting of the ACRS Subcommittee on Digital I&C Systems; Notice of Meeting

The ACRS Subcommittee on Digital I&C Systems will hold a meeting on May 17, 2016, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Tuesday, May 17, 2016—1:00 p.m. until 5:00 p.m.

The Subcommittee will review the cyber security informational SECY paper on Control of Access. The Subcommittee will hear presentations by and hold discussions with the NRC staff and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Christina Antonescu (Telephone 301–415–6792 or Email: *Christina.Antonescu@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 21, 2015, (80 FR 63846).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, MD. After registering with security, please contact Mr. Theron Brown (Telephone 240–888–9835) to be escorted to the meeting room.

Dated: April 20, 2016.

Mark L. Banks,

Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2016–09914 Filed 4–26–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS) Meeting of the ACRS Subcommittee on Regulatory Policies and Practices; Notice of Meeting

The ACRS Subcommittee on Regulatory Policies and Practices will hold a meeting on May 19, 2016, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Thursday, May 19, 2016—8:30 a.m. until 5:00 p.m.

The Subcommittee will discuss the State-of-the-Art Reactor Consequence Analyses Project (SOARCA) Project, Sequoyah (a PWR with Ice-Condenser Containment) plant. The Subcommittee will hear presentations by and hold discussions with the NRC staff and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Hossein Nourbakhsh (Telephone 301–415–5622 or Email: *Hossein.Nourbakhsh@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 21, 2015 (80 FR 63846).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, MD. After registering with security, please contact Mr. Theron Brown (Telephone 240–888–9835) to be escorted to the meeting room.

Dated: April 20, 2016.

Mark L. Banks,

Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2016–09886 Filed 4–26–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 99901385; EA–15–212; NRC–2016–0086]

In the Matter of C&D Technologies, Inc.

AGENCY: Nuclear Regulatory Commission.

ACTION: Confirmatory order; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing a confirmatory order (Order) to C&D Technologies, Inc. (C&D), to memorialize the agreements reached during an alternative dispute resolution mediation session held on March 10, 2016. This Order will resolve the issues that were identified during an NRC inspection at the C&D facility located in Blue Bell, Pennsylvania. This Order is effective 30 calendar days after its issuance.

DATES: Effective Date: The confirmatory order becomes effective on May 20, 2016.

ADDRESSES: Please refer to Docket ID NRC–2016–0086 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web Site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0086. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For questions about this Order, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "*ADAMS Public Documents*" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Gerald Gulla, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555–001; telephone: 301–415–2872, email: *Gerald.Gulla@nrc.gov.*

SUPPLEMENTARY INFORMATION: The text of the Order is attached.

Dated at Rockville, Maryland, this 20th day of April 2016.

For the Nuclear Regulatory Commission.

Patricia K. Holahan,

Director, Office of Enforcement.

UNITED STATES OF AMERICA NUCLEAR REGULATORY COMMISSION

In the Matter of) Docket No. 99901385
C&D Technologies, Inc.) EA–15–212

CONFIRMATORY ORDER

I

C&D Technologies, Inc., (C&D) provides Class 1E batteries for safety-related applications to nuclear power plants located in the United States. The C&D main office is located in Blue Bell, Pennsylvania.

This Confirmatory Order (Order) is the result of an agreement reached between C&D and the U.S. Nuclear Regulatory Commission (NRC) during an alternative dispute resolution (ADR) mediation session conducted on March 10, 2016.

II

From September 21 to September 25, 2015, the NRC conducted an inspection at the C&D facility in Blue Bell. The purpose of this limited-scope inspection was to assess C&D's compliance with the provisions of selected portions of title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, Appendix B "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," and 10 CFR part 21, "Reporting of Defects and Noncompliance."

On January 8, 2016, the NRC issued Inspection Report 99901385/2015–201 to C&D, which documented three apparent violations being considered for escalated enforcement action in accordance with the NRC Enforcement Policy.

The first apparent violation concerned C&D's failure to implement an adequate 10 CFR part 21 program to perform a timely and thorough evaluation of a deviation to identify defects, which if left uncorrected, could result in substantial safety hazards. The NRC identified that C&D's initial evaluation of a deviation in station battery cell separators lacked an adequate technical basis to support closing the evaluation in accordance with 10 CFR 21.21(a)(1). When C&D completed a more thorough evaluation of this deviation, a defect in the battery manufacturing process was identified. This defect was reported to the NRC in accordance with 10 CFR 21.21(d)(1); however, the report was made over 2½ years greater than the 60 day requirement. The second apparent violation concerned multiple additional instances where C&D failed to provide an adequate technical justification to support closing the evaluations of deviations in accordance with 10 CFR 21.21(a)(1). The third apparent violation concerned multiple additional instances where C&D failed to prepare and submit interim reports to the NRC when an evaluation could not be completed within 60 days from the date of discovery in accordance with 10 CFR 21.21(a)(2).

In response to the NRC's letter dated January 8, 2016, (Agencywide Documents Access and Management System (ADAMS) Accession No. ML15307A198), C&D requested the use of the NRC's ADR process to resolve these issues. Alternative Dispute Resolution is a process in which a neutral mediator with no decision-making authority assists the parties in reaching an agreement on resolving any differences regarding a dispute. This Order is being issued pursuant to the preliminary agreement reached between C&D and the NRC.

III

During the ADR mediation session, C&D and the NRC reached a preliminary settlement agreement. The elements of the agreement consisted of the following:

1. To ensure that C&D achieves full compliance for all currently identified violations, C&D will take the following actions:

A. By 30 calendar days from the issuance date of an Order, C&D shall confirm that all outstanding 10 CFR part 21 evaluations are complete and that all required interim reports are submitted in accordance with the timelines required by 10 CFR part 21.

B. By 45 calendar days from the issuance date of an Order, C&D shall review and revise, as necessary, all policies and procedures to provide reasonable assurance that Part 21 evaluations are conducted in accordance with 10 CFR 50, Appendix B quality assurance program requirements.

a. C&D shall define the Part 21 "discovery date" within their procedures as the date the issue is entered into the Part 21 process, corrective action system, nonconformance process, or reported in the customer complaint database, whichever occurs first.

b. C&D procedures shall provide reasonable assurance that the evaluation process of all deviations includes a documented technical evaluation and basis for why the identified deviation would or would not result in a substantial safety hazard, if left uncorrected.

C. By 45 calendar days from the issuance date of an Order, C&D shall contract an independent (not an employee or customer of C&D) third party expert to conduct an assessment of the C&D corrective action program (CAP), and the administrative controls and management controls in place to provide reasonable assurance of an effective part 21 program, including 10 CFR 50, Appendix B requirements. The initial assessment shall be completed by the end of the calendar year 2016 and assessments will continue annually.

D. C&D shall report the completion of items 1.A, 1.B and 1.C, in writing to the Director, Division of Construction Inspection and Operational Programs (DCIP), Nuclear Regulatory Commission (NRC), Office of New Reactors, no later than 75 calendar days from issuance of the Order.

2. To ensure that C&D senior management, first-line supervision and employees are committed to, and accountable for, complying with NRC requirements, and maintaining a robust safety culture, C&D will take the following actions:

A. By 30 calendar days from the issuance date of an Order, C&D shall issue a letter from President and Chief Executive Officer (CEO)[1] to employees in all C&D locations, working with nuclear-related activities, outlining C&D's management's expectations, including a commitment that all nuclear-related activities are performed and documented in a complete and accurate manner in accordance with approved procedures. C&D shall notify the DCIP Director no later than 30 calendar days after issuance of the letter and shall provide a copy of the letter to the DCIP Director. The letter shall address the following:

(1) Where the NRC inspection report can be found that describe the 2015 apparent violations;

(2) include a brief overview of the apparent violations;

(3) C&D senior management, mid-level managers and first-line supervisors expect all employees to follow approved policies and procedures; and

(4) C&D management has an expectation that all employees are to report procedure concerns to their supervisors (or to another appropriate level of management), and that supervisors are responsible for encouraging this reporting by staff and ensuring procedure issues are resolved appropriately and in a timely manner.

B. By 90 calendar days from the issuance date of an Order, Senior Management's commitment and expectations will be further reinforced through the use of conspicuously posted company-wide posters and/or other appropriate forms of communication. Communications will specifically discuss 10 CFR part 21 requirements, and best practices identified by C&D's evaluation of issues and violations (including root causes), corrective actions to prevent recurrence, and promote a strong safety culture.

C. Management expectations shall be further reinforced at the local level with an overt commitment from mid-level management and first-line supervisors regarding procedure adherence. Opportunities to communicate this commitment may include organizational all-hands meetings during which site managers and/or supervisors can convey the lessons learned from NRC inspections and any applicable industry assessments (*e.g.,* Nuclear Procurement Issues Committee (NUPIC)), and explain how to handle similar situations if and when they should arise in their organization or group.

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[1] In lieu of a letter to all employees, the NRC would consider it to be acceptable if C&D produced a video message from the CEO and other senior managers that would have wide-spread distribution and be shown at required all-hands meeting(s).

3. To ensure that C&D policies, procedures and work practices provide the necessary guidance to promote compliance with NRC requirements, C&D shall take the following actions:

A. By 180 calendar days of the issuance date of an Order, C&D shall enter the existing issue of procedure compliance into its corrective action program (CAP), and this issue shall be considered a significant condition adverse to quality. As a result, C&D shall conduct a formal root cause analysis of known procedure violations to determine the extent of condition of C&D work practices and identify corrective actions to improve procedure guidance. In addition, the extent of condition shall address the last five years of C&D's nuclear-related customer complaints, corrective actions, or nonconformances that meet the Part 21 definition of a deviation. C&D shall ensure that the extent of condition review is complete and that all 10 CFR part 21 deviations are identified and entered into C&D's Part 21 (A–14) procedure to ensure that they are adequately evaluated for reportable defects. By 30 calendar days of corrective action completion, C&D shall provide the results of its root cause and extent of condition report to the DCIP Director.

B. By 60 calendar days of the issuance date of an Order, C&Ds corrective action program shall be revised to have the ability to trend 10 CFR part 21 related issues, such as failure to follow 10 CFR part 21 procedure requirements or failure to enter a deviation into the 10 CFR part 21 process.

4. To ensure that all C&D employees understand their roles and responsibilities regarding compliance with NRC requirements, C&D will provide training and other forms of continuous reinforcement to its employees:

By 90 calendar days from the issuance date of an Order, C&D will complete the development of a training program as described below. The initial training shall be submitted to the NRC for review and comment before being implemented. The NRC will review the draft training provided by C&D within 10 business days. The Initial training shall then be conducted and documented for all current employees and supervisors no later than 30 calendar days from the completion of the NRC review. C&D shall report to the DCIP Director by telephone within 7 calendar days of completion of the initial training.

A. Training (initial and annual) shall cover the basic regulatory requirements of 10 CFR; the legal authority granted to the NRC to inspect for compliance; the enforcement actions that can be taken against the company, the customer and company employees for noncompliance; 10 CFR 50, Appendix B and 10 CFR part 21 requirements; and the associated C&D procedures. This shall be documented and provided to all employees involved in nuclear-related work activities, including management.

B. Develop, implement and document initial training and annual refresher training for item 4.A.

C. For employees involved in nuclear-related activities (including supervisors) hired after the date of initial training completion, the initial training shall be provided and documented within 45 calendar days of hire.

D. For 3 years following the effective date of the Order, C&D shall assess the effectiveness of training and procedure compliance by reviewing and trending information obtained from C&D's CAP.

In addition to the elements described above, C&D has taken or committed to take the following corrective actions.

1. Complete implementation of an improved process that customers use to report information (*i.e.,* the iSight system) to C&D for battery issues. This process shall assure prompt entry and classification of issues to determine if the issue is a deviation, if applicable.

2. Complete implementation of a new 10 CFR part 21 process that includes biweekly meetings that are attended by executive management, and logs of actions and schedules for reporting to the NRC.

3. Complete implementation of new qualification report documentation to reconstitute the design basis of the K and L battery product lines by linking the specification requirements to specific test results required by the Institute of Electrical and Electronics Engineers (IEEE) specifications.

4. Complete implementation of new internal reporting requirements. Quality assurance issues shall be reported to the CEO.

5. Hold monthly corrective action meetings with plant managers and the executive team to ensure timely correction of identified issues.

6. Complete implementation of more robust Safety Committee meetings conducted with particular attention paid to due dates. In addition, the process for initial reporting of customer identified issues has been established so that the Quality Systems manager conducts the first review of the issue as soon as correspondence begins with a nuclear customer.

7. Complete institution of a third party 10 CFR part 21 and Appendix B audit program, using experienced and qualified personnel reporting directly to the CEO and General Counsel. The audits shall be executed annually. Inputs to the audits will include all customer communications, customer complaint information, and 10 CFR part 21 and Safety Committee records. The initial audit shall occur by the end of March 2016 for the 10 CFR part 21 program and by September 2016 of Appendix B to 10 CFR part 50.

Based on the actions described above, and the commitments described in Section V below, the NRC agrees to the following conditions:

1. The NRC will consider this Order as an escalated enforcement action for the purposes of determining future enforcement action per the NRC Enforcement Policy,

2. The NRC will refrain from issuing a proposed imposition of a civil penalty and a Notice of Violation for the above-referenced apparent violations.

On April 12, 2016, C&D consented to issuing this Order with the commitments, as described in Section V below. C&D further agreed that this Order is to be effective 30 calendar days after its issuance, the agreement memorialized in this Order settles the matter between the parties, and that C&D has waived its right to a hearing.

IV

I find that C&D's actions completed or committed to take, as described in Section III above, combined with the commitments as set forth in Section V are acceptable and necessary, and conclude that with these commitments the public health and safety are reasonably assured. In view of the foregoing, I have determined that public health and safety require that C&D's commitments be confirmed by this Order. Based on the above and C&D's consent, this Order is effective 30 calendar days after its issuance.

V

Accordingly, pursuant to Sections 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR parts 21, and 50, *it is hereby ordered that:*

A. Compliance with 10 CFR part 21

1. By 45 calendar days from the issuance date of this Order, C&D shall

confirm that all outstanding 10 CFR part 21 evaluations are complete and that all required interim reports are submitted in accordance with the timelines required by 10 CFR part 21.

2. By 45 calendar days from the issuance date of this Order, C&D shall review and revise, as necessary, all policies and procedures to provide reasonable assurance that Part 21 evaluations are conducted in accordance with 10 CFR 50, Appendix B quality assurance program requirements.

a. C&D shall define the Part 21 "discovery date" within their procedures as "the date the issue is entered into the Part 21 process, corrective action system, nonconformance process, or reported in the customer complaint database, whichever occurs first."

b. C&D procedures shall provide reasonable assurance that the evaluation process used for all deviations includes a documented technical evaluation and basis for why the identified deviation would or would not result in a substantial safety hazard, if left uncorrected.

3. By 45 calendar days from the issuance date of this Order, C&D shall contract an independent third party expert (not an employee or customer of C&D) to conduct an assessment of the C&D corrective action program, and the administrative controls and management controls in place to provide reasonable assurance of an effective Part 21 program, including 10 CFR 50, Appendix B requirements. The initial assessment shall be completed by the end of the calendar year 2016 and assessments will continue annually thereafter.

4. C&D shall report the completion of items A.1, A.2, and A.3, in writing to the DCIP Director no later than 75 calendar days from issuance of this Order.

B. Communications

1. By 45 calendar days from the issuance date of this Order, C&D shall issue a letter and/or video message from the President and CEO to employees in all C&D locations working with nuclear-related activities, outlining C&D's management's expectations, including a commitment that all nuclear-related activities are performed and documented in a complete and accurate manner in accordance with approved procedures. C&D shall notify the DCIP Director no later than 30 calendar days after issuance of the letter and shall provide a copy of the letter to the DCIP Director. The letter shall address the following:

a. how to obtain the NRC inspection report that describes the 2015 apparent violations;

b. a brief overview of the apparent violations;

c. a statement that C&D senior management, mid-level managers, and first-line supervisors expect all employees to follow approved policies and procedures; and

d. a statement that C&D management has an expectation that all employees are to report procedure concerns to their supervisors, or to another appropriate level of management, and that supervisors are responsible for encouraging this reporting by staff, and ensuring procedure issues are resolved appropriately and in a timely manner.

2. By 90 calendar days from the issuance date of this Order, C&D senior management's commitment and expectations will be further reinforced through the use of conspicuously posted company-wide posters and/or other appropriate forms of communication. Communications will specifically discuss 10 CFR part 21 requirements, and best practices identified by C&D's evaluation of issues and violations (including root causes), corrective actions to prevent recurrence, and promote a strong safety culture.

C. Work Processes

1. C&D shall ensure that the existing issue of procedure compliance has been entered into its CAP, and this issue shall be considered a significant condition adverse to quality. As a result, within 180 days of the issuance date of this Order, C&D shall conduct a formal root cause analysis of known procedure violations to determine the extent of condition of C&D work practices and identify corrective actions to improve procedure guidance. In addition, the extent of condition shall address the last five years of C&D's nuclear-related customer complaints, corrective actions, or nonconformances that meet the Part 21 definition of a "deviation." C&D shall ensure that the extent of condition review is complete and that all 10 CFR part 21 deviations are identified and entered into C&D's 10 CFR part 21 program to ensure that they are adequately evaluated for reportable defects. By 30 calendar days of corrective action completion, C&D shall provide the results of its root cause and extent of condition report to the DCIP Director.

2. By 60 calendar days of the issuance date of this Order, C&Ds CAP shall be revised to have the ability to trend 10 CFR part 21 related issues, such as failure to follow 10 CFR part 21 procedure requirements or failure to enter a deviation into the 10 CFR part 21 process.

D. Training

1. By 90 calendar days from the issuance date of this Order, C&D will develop a training program as described below. The training program, including the initial training, shall be submitted to the NRC for review and comment before being implemented. Within 10 business days of submission, the NRC will perform an initial review and provide comments to C&D. Within 30 days of receiving NRC comments, C&D shall adequately address these comments in writing, at which time the NRC will provide a final review of the program. The NRC will inform C&D of its approval of the training program in writing and by telephone within 10 days of re-submittal by C&D. The initial training shall then be conducted and documented for all current employees and supervisors no later than 30 calendar days from the NRC final approval date. C&D shall report to the DCIP Director in writing and by telephone within 7 calendar days of completion of the initial training.

a. Training (initial and annual) shall cover the basic requirements (*e.g.,* what they are and how they apply) of 10 CFR 50, Appendix B and 10 CFR part 21; the legal authority granted to the NRC to inspect for compliance; the enforcement actions that can be taken against the company, the customer and company employees for noncompliance; and the associated C&D procedures. This training shall be provided to all employees involved in nuclear-related work activities, including management.

b. Develop, implement and document initial training and annual refresher training for item D.1.a.

c. For employees involved in nuclear-related activities, including supervisors, who are hired after the date of initial training completion, the initial training shall be provided and documented within 45 calendar days of hire.

d. For three years following the effective date of this Order, C&D shall assess the effectiveness of training and procedure compliance by reviewing and trending information obtained from C&D's CAP.

The terms of this Order apply to the successors and assigns of C&D.

The Director, Office of Enforcement, may, in writing, relax or rescind any of the above conditions upon demonstration by C&D of good cause.

VI

In accordance with 10 CFR 2.202 and 10 CFR 2.309, any person adversely affected by this Order, other than C&D,

may request a hearing within 30 days of the issuance date of this Order. Where good cause is shown, consideration will be given to extending the time to request a hearing. A request for extension of time must be directed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, and include a statement of good cause for the extension.

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007), as amended by 77 FR 46562; August 3, 2012 (codified in pertinent part at 10 CFR part 2, subpart C). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten (10) days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital identification (ID) certificate. Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* System requirements for accessing the E-Submittal server are detailed in NRC's "Guidance for Electronic Submission," which is available on the agency's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene through the EIE. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time (ET) on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, any others who wish to participate in the proceeding (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the "Contact Us" link located on the NRC's Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at (866) 672–7640. The NRC Meta System Help Desk is available between 8:00 a.m. and 8:00 p.m., ET, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is available to the public at *http://ehd1.nrc.gov/ehd/,* unless excluded pursuant to an order of the Commission or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. However, in some instances, a request to intervene will require including information on local residence in order to demonstrate a proximity assertion of interest in the proceeding. With respect to copyrighted works, participants are requested not to include copyrighted materials in their submission, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application.

If a person other than the licensee requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.309(d) and (f).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue a separate Order designating the time and place of any hearings, as appropriate. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section V above shall be final 30 days after issuance of this Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section V shall be final when the extension expires if a hearing request has not been received.

Dated at Rockville, Maryland, this 20th day of April 2016.

For the Nuclear Regulatory Commission.

Patricia K. Holahan, Director,

Office of Enforcement.

[FR Doc. 2016–09917 Filed 4–26–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 52–017; NRC–2008–0066]

Dominion Virginia Power; North Anna, Unit 3; Combined License Application

AGENCY: Nuclear Regulatory Commission.

ACTION: Combined license application; receipt.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is giving notice once each week for four consecutive weeks of the North Anna Unit 3 combined license (COL) application from Dominion Virginia Power (Dominion).

DATES: April 27, 2016.

ADDRESSES: Please refer to Docket ID NRC–2008–0066 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2008–0066. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "*ADAMS Public Documents*" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: James Shea, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–1388, email: *James.Shea@nrc.gov.*

SUPPLEMENTARY INFORMATION: The Virginia Electric and Power Company, doing business as Dominion Virginia Power (Applicant) has filed an application for a COL with the NRC under Section 103 of the Atomic Energy Act of 1954, as amended, and part 52 of title 10 of the *Code of Federal Regulations* (10 CFR), "Licenses, Certifications, and Approvals for Nuclear Power Plants." Through the Application, which is currently under review by the NRC staff, the Applicant seeks to construct and operate an Economic Simplified Boiling-Water Reactor at the North Anna Power Station, which is located in Louisa County, Virginia. An applicant may seek a COL in accordance with subpart C of 10 CFR part 52. The information submitted by the applicant includes certain administrative information, such as financial qualifications submitted pursuant to 10 CFR 52.77, as well as technical information submitted pursuant to 10 CFR 52.79. These notices are being provided in accordance with the requirements in 10 CFR 50.43(a)(3).

Dated at Rockville, Maryland, this 21th day of April, 2016.

For the Nuclear Regulatory Commission.

Ronaldo Jenkins,

Chief, Licensing Branch 3, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. 2016–09847 Filed 4–26–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–389; NRC–2016–0085]

Florida Power & Light Company; St. Lucie Plant, Unit No. 2

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an exemption in response to a December 30, 2014, request from Florida Power & Light Company for the use of a different fuel rod cladding material (AREVA M5®).

ADDRESSES: Please refer to Docket ID NRC–2016–0085 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2016–0085. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "*ADAMS Public Documents*" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:*You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Perry H. Buckberg; telephone: 301–415–1383; email: *Perry.Buckberg@nrc.gov*; or Robert L. Gladney; telephone: 301–415–1022; email: *Robert.Gladney@nrc.gov.* Both are staff of the Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

I. Background

Florida Power & Light Company (the licensee) is the holder of Renewed Facility Operating License No. NPF–16, which authorizes operation of the St. Lucie Plant, Unit No. 2 (PSL–2). The license provides, among other things, that the facility is subject to all rules, regulations, and orders of the NRC now or hereafter in effect. The facility consists of a pressurized-water reactor (PWR) located in St. Lucie County, Florida.

II. Request/Action

Pursuant to § 50.12, "Specific exemptions," of title 10 of the *Code of Federal Regulations* (10 CFR), the licensee, by letter dated December 30, 2014 (ADAMS Accession No. ML15002A091), requested an exemption from the requirements of 10 CFR 50.46, "Acceptance criteria for emergency core cooling systems [ECCS] for light-water nuclear power reactors," and 10 CFR part 50, Appendix K, "ECCS Evaluation Models," to allow the use of fuel rods clad with the AREVA M5® zirconium alloy in future core reload applications for PSL–2. The regulations in 10 CFR 50.46 contain acceptance criteria for the ECCS for reactors fueled with Zircaloy or ZIRLO™ fuel rod cladding material. In addition, Appendix K to 10 CFR part 50 requires that the Baker-Just equation be used to predict the rates of energy release, hydrogen concentration, and cladding oxidation from the metal-water reaction. The Baker-Just equation assumes the use of a zirconium alloy, which is a material different from the M5® zirconium alloy. The licensee requested the exemption because these regulations do not have provisions for the use of fuel rods clad in a material other than Zircaloy or ZIRLO™. Since the material designations of M5® zirconium alloy are different from the designations for Zircaloy or ZIRLO™, a plant-specific exemption is required to support the reload applications for PSL–2.

The exemption request relates solely to the cladding material specified in these regulations (*i.e.,* fuel rods with Zircaloy or ZIRLO™ cladding material). In its letter dated December 30, 2014, the licensee stated that this exemption was requested in order, "to allow the use of a zirconium alloy other than Zircaloy or [ZIRLO™] for fuel cladding material at St. Lucie Unit 2." This exemption would provide for the application of the acceptance criteria of 10 CFR 50.46 and Appendix K to 10 CFR part 50 to fuel assembly designs using M5® zirconium alloy fuel rod cladding material.

In addition to the exemption request in the letter dated December 30, 2014, the licensee also requested an amendment to revise the Technical Specifications (TSs) to allow for the use of AREVA fuel at PSL–2. The NRC staff has addressed the requested amendment in separate correspondence dated April 19, 2016 (ADAMS Accession No. ML16063A121).

III. Discussion

Pursuant to 10 CFR 50.12, the Commission may, upon application by any interested person, grant exemptions from the requirements of 10 CFR part 50, which are authorized by law, will not present an undue risk to the public health and safety, and are consistent with the common defense and security. Paragraph (a)(2)(ii) of 10 CFR 50.12 states that the Commission will not consider granting an exemption unless special circumstances are present, such as when application of the regulation in the particular circumstance is not necessary to achieve the underlying purpose of the rule.

A. Special Circumstances

Special circumstances, in accordance with 10 CFR 50.12(a)(2)(ii), are present whenever application of the regulation in the particular circumstances is not necessary to achieve the underlying purpose of the rule. The underlying purpose of 10 CFR 50.46 and Appendix K to 10 CFR part 50 is to establish acceptance criteria for ECCS performance. The regulations in 10 CFR 50.46 and Appendix K are not directly applicable to M5® cladding material because the M5® cladding material is not specified in 10 CFR 50.46 or presumed in the Baker-Just equation required by paragraph I.A.5 of 10 CFR part 50, Appendix K. The evaluations described in the following sections of this exemption, however, show that the intent of the regulation is met in that subject to certain conditions, the acceptance criteria are valid for M5® zirconium-based alloy cladding, the material is less susceptible to embrittlement, and the Baker-Just equation conservatively bounds scenarios following a loss-of-coolant accident (LOCA) for rods with M5® cladding material. Thus, a strict application of the rule (which would preclude the applicability of ECCS performance acceptance criteria to, and the use of, M5® clad fuel rods) is not necessary to achieve the underlying purposes of 10 CFR 50.46 and Appendix K of 10 CFR part 50. The purpose of these regulations is achieved through the application of the requirements for the use of M5® fuel rod cladding material. Therefore, the special circumstances required by 10 CFR 50.12(a)(2)(ii) for the granting of an exemption exist.

B. The Exemption Is Authorized by Law

This exemption would allow the use of fuel rods clad with the AREVA M5® fuel rod cladding material in future core reload applications for PSL–2. Section 50.12 of 10 CFR allows the NRC to grant exemptions from the requirements of 10 CFR part 50 provided that special circumstances are present. The NRC staff determined that granting the licensee's proposed exemption would not result in a violation of the Atomic Energy Act of 1954, as amended, or the Commission's regulations. Therefore, the exemption is authorized by law.

C. The Exemption Presents No Undue Risk to Public Health and Safety

Section 50.46 of 10 CFR requires that each boiling or pressurized light-water nuclear power reactor fueled with uranium oxide pellets within cylindrical Zircaloy or ZIRLO™ cladding must be provided with an ECCS that must be designed so that its calculated cooling performance following postulated LOCAs conforms to the criteria set forth in paragraph (b) of that section. The underlying purpose of 10 CFR 50.46 is to establish acceptance criteria for adequate ECCS performance at nuclear reactors.

Framatome Cogema Fuels (AREVA) submitted topical report BAW–10227P–A, Revision 0, "Evaluation of Advanced Cladding and Structural Material (M5®) in PWR Reactor Fuel," to the NRC for review and approval by letter dated September 30, 1997. The NRC staff documented its approval of BAW–10227P–A, Revision 0 in a safety evaluation (SE) dated February 4, 2000 (ADAMS Accession No. ML003681490) and concluded that 10 CFR 50.46 and 10 CFR part 50, Appendix K criteria are applicable to M5® fuel cladding, subject to compliance with specified burnup conditions. The NRC-accepted version of BAW–10227P–A, Revision 0 was submitted to the NRC by letter dated February 11, 2000 (ADAMS Accession No. ML003685828). BAW–10227P–A, Revision 1, dated June 2003, as noted by letter dated April 19, 2004 (ADAMS Accession No. ML15162B047), is a subsequent revision to BAW–10227P–A, Revision 0 and incorporated the portion of the NRC's approval provided in the NRC SE for BAW–10186P–A, Revision 1, Supplement 1, "Extended Burnup Evaluation," dated June 18, 2003 (ADAMS Accession No. ML031700090), in which the applicable restrictions on burnup were removed. Additionally, in an SE dated May 5, 2004 (ADAMS Accession No. ML041260560), the NRC staff approved topical report BAW–10240(P), "Incorporation of M5 Properties in Framatome ANP [AREVA] Approved Methods," which further addressed M5® material properties with respect to LOCA applications and included specified conditions.

The specific conditions that address the use of M5® under approved methods that were provided in the SE for BAW–10240(P) are: (1) The corrosion limit, as predicted by the best-estimate model, will remain below 100 microns for all locations of the fuel; (2) all of the conditions listed in the NRC SEs for all AREVA methodologies used for M5® fuel analysis will continue to be met; (3) all AREVA methodologies will be used only within the range for which M5® data was acceptable and for which the verifications discussed in the applicable topical reports were performed; and (4) the burnup limit for implementation of M5® is 62 gigawatt-days per metric ton uranium metal (GWd/MTU). The staff determined that the licensee has satisfied these conditions. The corrosion limit stated in condition (1) is verified by the licensee for each reload as required by TS 6.9.1.11, "Core Operating Limits Report (COLR)." The conditions from NRC-approved SEs stated in condition (2) are incorporated as restrictions in AREVA design procedures and guidelines that will control the core reload designs for PSL–2, which are also verified for each reload as required by the COLR. The restrictions on the use of AREVA methodologies stated as condition (3) are also incorporated as restrictions in AREVA design procedures and guidelines that will control the core reload designs for PSL–2, which are also verified for each reload as required by the COLR. Finally, the burnup limit stated in condition (4) is currently part of AREVA's design processes (as stated by the licensee), and is also verified as part of the cycle-specific reload analysis as required by the COLR.

In the exemption granted for PSL, Unit No. 1, for the application and use of AREVA M5® fuel rod cladding material, dated March 31, 2014 (ADAMS Accession No. ML14064A125), the NRC staff described the applicable results from the LOCA research program completed at the Argonne National Laboratory. The results showed that cladding corrosion and associated hydrogen pickup had a significant impact on post-quench ductility. The research also provided further evidence of favorable corrosion and hydrogen pickup characteristics of M5® as compared with standard Zircaloy and that, due to its favorable hydrogen pickup, fuel rods with M5® zirconium-based alloy cladding are less susceptible to hydrogen-enhanced beta layer embrittlement, a new embrittlement mechanism. In addition, the exemption documented that the 10 CFR 50.46(b) acceptance criteria (*i.e.,* 2200 degrees Fahrenheit and 17-percent equivalent cladding reacted) remain conservative up to the current burnup limit of 62 GWd/MTU and that the acceptance criteria within 10 CFR 50.46 remain valid for the M5® alloy material. As a result, the NRC staff found that the underlying purpose of the rule—to maintain a degree of post-quench ductility in the fuel cladding material through ECCS performance criteria—would be met if an exemption were granted to allow those criteria to apply to M5® clad fuel. This conclusion remains valid for an exemption for PSL–2 for the application and use of AREVA M5® fuel rod cladding material.

In addition, as stated by the licensee in its application, "FPL [Florida Power & Light Company], in conjunction with AREVA NP Inc. (AREVA), will utilize NRC[-]approved methods for the reload design process, for PSL–2 reload cores containing M5® fuel rod cladding, to ensure safety analysis limits are met for operation within the operating limits specified in the Technical Specifications." The licensee also stated that it will "ensure compliance with the respective acceptance criteria" and that "the intent of 10 CFR 50.46 and 10 CFR 50, Appendix K will continue to be satisfied." Therefore, for the reasons stated above, granting the exemption request will ensure that the underlying purpose of the rule is achieved for PSL–2.

Paragraph I.A.5 of Appendix K to 10 CFR part 50 states that the rate of energy release, hydrogen concentration, and cladding oxidation from the metal-water reaction shall be calculated using the Baker-Just equation. The approved AREVA topical reports show that due to the similarities in the chemical composition of the advanced zirconium-based M5® alloy and Zircaloy, the application of the Baker-Just equation in the analysis of the M5® clad fuel rods will continue to conservatively bound all post-LOCA scenarios. For the reasons stated above, granting the exemption request will ensure that the Baker-Just equation can be applied to M5® clad fuel and that the underlying purpose of the rule is achieved for PSL–2.

Based upon results of metal-water reaction testing and mechanical testing, which ensure the applicability of 10 CFR 50.46 acceptance criteria and 10 CFR part 50, Appendix K, methods, the NRC staff finds it acceptable to grant an exemption from the requirements of 10 CFR 50.46 and Appendix K to 10 CFR part 50 to allow these regulations to apply to, and enable the use of, fuel rods with M5® zirconium-based alloy at PSL–2. Therefore, the exemption presents no undue risk to public health and safety.

D. The Exemption Is Consistent With the Common Defense and Security

The licensee's exemption request is only to allow the application of the aforementioned regulations to an improved fuel rod cladding material. In its letter dated December 30, 2014, the licensee stated that all the requirements and acceptance criteria will be maintained and that it would continue to handle and control special nuclear material in the fuel product in accordance with its approved procedures. This change to the reactor core internals is adequately controlled by NRC requirements and is not related to security issues. Therefore, the NRC staff has determined that this exemption does not impact common defense and security and is consistent with the common defense and security.

E. Environmental Considerations

The NRC staff determined that the exemption discussed herein meets the eligibility criteria for the categorical exclusion set forth in 10 CFR 51.22(c)(9) because it is related to a requirement concerning the installation or use of a facility component located within the restricted area, as defined in 10 CFR part 20, and the granting of this exemption involves: (i) No significant hazards consideration, (ii) no significant change in the types or a significant increase in the amounts of any effluents that may be released offsite, and (iii) no significant increase in individual or cumulative occupational radiation exposure. Therefore, in accordance with 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the NRC's consideration of this exemption request. The basis for the NRC staff's determination is discussed as follows with an evaluation against each of the requirements in 10 CFR 51.22(c)(9)(i)–(iii).

Requirements in 10 CFR 51.22(c)(9)(i)

The NRC staff evaluated the issue of no significant hazards consideration, using the standards described in 10 CFR 50.92(c), as presented below:

1. Does the proposed exemption involve a significant increase in the

probability or consequences of an accident previously evaluated?

The proposed changes for PSL–2 revise TS 5.3.1 to include M5® cladding, delete the linear heat rate surveillance requirement with W(z) in TS 4.2.1.3, and include previously approved AREVA topical reports in the list of COLR methodologies in TS 6.9.1.11. [Another] change is in TS License Condition 3.N, which is related to future analysis of the current fuel and is considered an administrative change, all as a result of changing the fuel supplier.

The fuel assembly design is not an initiator to any accident previously evaluated. Therefore, there is no significant increase in the probability of any accident previously evaluated. However, the fuel design parameters and the correlations used in the analyses supporting the operation of PSL–2 with the new proposed AREVA fuel are dependent on the fuel assembly design. All the analyses, potentially impacted by the fuel design, have been re-analyzed using the correlations and the methodology applicable to the proposed fuel design and previously approved by the NRC for similar applications. There are no changes to any limits specified in the TSs. M5® cladding to be used in the proposed AREVA fuel design has been previously approved by the NRC for PWR applications, including the St. Lucie Plant, Unit No. 1. The core design peaking factors remain unchanged from the current analyses values, except for the large break LOCA, which is shown to meet all the 10 CFR 50.46 criteria with the increased peak linear heat rate limit.

Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed exemption create the possibility of a new or different kind of accident from any accident previously evaluated?

No new or different accidents result from utilizing the proposed AREVA CE [Combustion Engineering] 16x16 fuel design [and M5® cladding]. Other than the fuel design change, the proposed exemption does not involve a physical alteration of the plant or plant systems (*i.e.*, no new or different type of equipment will be installed which would create a new or different kind of accident). The change to the linear heat rate surveillance requirement, when operating on excore detector monitoring system, and the use of M5® cladding do not affect or create any accident initiator. There is no change to the methods governing normal plant operation and the changes do not impose any new or different operating requirements. The core monitoring system remains unchanged.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed exemption involve a significant reduction in a margin of safety?

The changes proposed in this exemption are related to the fuel design with M5® cladding and the methodology supporting the analysis of accidents impacted by the fuel design change. The analysis methods used are previously approved by the NRC for similar applications. The change to the surveillance requirement for the linear heat rate does not change any accident analysis requirements. The fuel design limits related to the DNBR [departure from nucleate boiling ratio] and fuel centerline melt remain consistent with the limits previously approved for the proposed fuel design change. The overpressure limits for the reactor coolant system integrity and the containment integrity remain unchanged. All of the analyses performed to support the fuel design change meet all applicable acceptance criteria. The LOCA analyses, with the peak linear heat rate limit increase, continue to meet all of the applicable 10 CFR 50.46 acceptance criteria, and thus the proposed changes do not affect margin of safety for any accidents previously evaluated.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

Based on the above, the NRC staff concludes that the proposed exemption presents no significant hazards consideration under the standards set forth in 10 CFR 50.92(c), and, accordingly, a finding of no significant hazards consideration is justified.

Requirements in 10 CFR 51.22(c)(9)(ii)

The proposed exemption would allow the use of M5® fuel rod cladding material in the PSL–2 reactor. M5® has essentially the same properties as the currently licensed Zircaloy fuel rod cladding. The use of the M5® fuel rod cladding material will not significantly change the types of effluents that may be released offsite, or significantly increase the amount of effluents that may be released offsite. Therefore, the provisions of 10 CFR 51.22(c)(9)(ii) are satisfied.

Requirements in 10 CFR 51.22(c)(9)(iii)

The proposed exemption would allow the use of the M5® fuel rod cladding material in the PSL–2 reactor core. M5® has essentially the same properties as the currently used Zircaloy cladding. The use of the M5® fuel rod cladding material will not significantly increase individual occupational radiation exposure, or significantly increase cumulative occupational radiation exposure. Therefore, the provisions of 10 CFR 51.22(c)(9)(iii) are satisfied.

IV. Conclusions

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12, the exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. Also, special circumstances, as required by 10 CFR 50.12(a)(2)(ii), are present. Therefore, the Commission hereby grants the licensee an exemption from the requirements of 10 CFR 50.46 and Appendix K to 10 CFR part 50, to allow the use of M5® fuel rod cladding material at PSL–2.

This exemption is effective upon issuance.

Dated at Rockville, Maryland, this 19th of April, 2016.

For the Nuclear Regulatory Commission.

Anne T. Boland,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2016–09851 Filed 4–26–16; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2016–123 and CP2016–156; Order No. 3255]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the addition of Priority Mail Contract 208 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* April 28, 2016.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30-.35, the Postal Service filed a formal request and associated supporting information to add Priority Mail Contract 208 to the competitive product list.[1]

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. Request, Attachment B.

To support its Request, the Postal Service filed a copy of the contract, a copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket Nos. MC2016–123 and CP2016–156 to consider the Request pertaining to the proposed Priority Mail Contract 208 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than April 28, 2016. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Christopher C. Mohr to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2016–123 and CP2016–156 to consider the matters raised in each docket.
2. Pursuant to 39 U.S.C. 505, Christopher C. Mohr is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).
3. Comments are due no later than April 28, 2016.
4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,

Secretary.

[FR Doc. 2016–09735 Filed 4–26–16; 8:45 am]

BILLING CODE 7710–FW–P

RAILROAD RETIREMENT BOARD

Proposed Collection; Comment Request

Summary: In accordance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 which provides opportunity for public comment on new or revised data collections, the Railroad Retirement Board (RRB) will publish periodic summaries of proposed data collections.

Comments are invited on: (a) Whether the proposed information collection is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the RRB's estimate of the burden of the collection of the information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden related to the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

1. Title and purpose of information collection: Evidence of Marital Relationship, Living with Requirements; OMB 3220–0021.

To support an application for a spouse or widow(er)'s annuity under Sections 2(c) or 2(d) of the Railroad Retirement Act, an applicant must submit proof of a valid marriage to a railroad employee. In some cases, the existence of a marital relationship is not formalized by a civil or religious ceremony. In other cases, questions may arise about the legal termination of a prior marriage of the employee, spouse, or widow(er). In these instances, the RRB must secure additional information to resolve questionable marital relationships. The circumstances requiring an applicant to submit documentary evidence of marriage are prescribed in 20 CFR 219.30.

In the absence of documentary evidence, the RRB needs to determine if a valid marriage existed between a spouse or widow(er) annuity applicant and a railroad employee. The RRB utilizes Forms G–124, Individual Statement of Marital Relationship; G–124a, Certification of Marriage Information; G–237, Statement Regarding Marital Status; G–238, Statement of Residence; and G–238a, Statement Regarding Divorce or Annulment, to secure the needed information. One response is requested of each respondent. Completion is required to obtain benefits. The RRB proposes minor non-burden impacting changes to the forms in the collection.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

Form number	Annual responses	Time (minutes)	Burden (hours)
G–124 (in person)	125	15	31
G–124 (by mail)	75	20	25
G–124a	300	10	50
G–237 (in person)	75	15	19
G–237 (by mail)	75	20	25
G–238 (in person)	150	3	8
G–238 (by mail)	150	5	13
G–238a	150	10	25
Total	1,100		196

* Forms G–124, G–237, G–238, and G–238a can be completed either with assistance from RRB personnel during an in-office interview or by mail.

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[1] Request of the United States Postal Service to Add Priority Mail Contract 208 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, April 20, 2016 (Request).

2. Title and purpose of information collection: Voluntary Customer Surveys in Accordance with E.O. 12862; OMB 3220–0192.

In accordance with Executive Order 12862, the Railroad Retirement Board (RRB) conducts a number of customer surveys designed to determine the kinds and quality of services our beneficiaries, claimants, employers and members of the public want and expect, as well as their satisfaction with existing RRB services. The information collected is used by RRB management to monitor customer satisfaction by determining to what extent services are satisfactory and where and to what extent services can be improved. The surveys are limited to data collections that solicit strictly voluntary opinions, and do not collect information which is required or regulated. The information collection, which was first approved by the Office of Management and Budget (OMB) in 1997, provides the RRB with a generic clearance authority. This generic authority allows the RRB to submit a variety of new or revised customer survey instruments (needed to timely implement customer monitoring activities) to the Office of Management and Budget (OMB) for expedited review and approval.

The average burden per response for customer satisfaction activities is estimated to range from 2 minutes for a Web site questionnaire to 2 hours for participation in a focus group. The RRB estimates an annual burden of 1,620 annual respondents totaling 731 hours for the generic customer survey clearance.

Additional Information or Comments: To request more information or to obtain a copy of the information collection justification, forms, and/or supporting material, contact Dana Hickman at (312) 751–4981 or *Dana.Hickman@RRB.GOV.* Comments regarding the information collection should be addressed to Charles Mierzwa, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092 or emailed to *Charles.Mierzwa@RRB.GOV.* Written comments should be received within 60 days of this notice.

Charles Mierzwa,

Chief of Information Resources Management.

[FR Doc. 2016–09804 Filed 4–26–16; 8:45 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77680; File No. SR–NYSEMKT–2016–17]

Self-Regulatory Organizations; NYSE MKT LLC; Order Approving a Proposed Rule Change, as Modified by Amendment No. 1, To Establish Procedures for the Allocation of Cages to Co-Located Users, Including the Waiver of Certain Fees, and To Amend the Visitor Security Escort Fee

April 21, 2016.

I. Introduction

On February 23, 2016 NYSE MKT LLC ("the Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change to establish procedures for the allocation of cages to co-located Users, including the waiver of certain fees, and to amend the visitor security escort fee. On March 1, 2016, the Exchange filed Amendment No. 1 to the proposed rule change. The proposed rule change, as modified by Amendment No. 1, was published for comment in the **Federal Register** on March 11, 2016.[3] There were no comments on the proposed rule change. This order approves the proposed rule change, as modified by Amendment No. 1.

II. Background and Description of the Proposal, as Modified by Amendment No. 1

The Exchange proposes to establish procedures for the allocation of cages to its co-located Users,[4] including the waiver of certain fees subject to specified conditions, and to amend the visitor security escort fee.[5] The Exchange proposes to amend the NYSE MKT Equities Price List ("Price List") and the NYSE Amex Options Fee Schedule ("Fee Schedule") to reflect the changes.[6]

As more fully set forth in the Notice, the Exchange offers Users the ability to rent cages to house their cabinets in the Data Center,[7] and historically has offered these cages on a first come/first serve basis.[8] The Exchange states that a cage typically is purchased by a User that has several cabinets within the Data Center and wishes to arrange its cabinets contiguously while also enhancing privacy around its cabinets.[9] The Exchange offers three cage sizes, corresponding to the number of cabinets housed therein, and charges fees for the cages based on the size.[10] The physical footprint of each cage is greater than that of the cabinets that it houses, as each cage is constructed so as to include aisles around the purchasing User's cabinets, for accessibility and to comply with safety regulations.[11] In order to offer the cages, the Exchange must have sufficient contiguous open space available for the cage.[12]

In 2015, the Exchange determined that to continue to be able to meet its obligation to accommodate demand, and in particular to make available more contiguous, larger spaces for new and existing Users, it would exercise its right to move some Users' equipment within the Data Center (the "Migration").[13] The Exchange established procedures to manage the Migration process, and continues to implement them.[14] The Exchange states that, notwithstanding the Migration, contiguous open space will still be limited, and may become more limited over time.[15]

Proposed Cage Allocation Procedure

The Exchange has proposed to establish procedures governing the allocation of cages should the currently available open contiguous space in the Data Center be insufficient to house a new cage or if the open contiguous space available is sufficiently limited such that the Exchange cannot both provide new cages and satisfy all User demand for other co-location services.[16] Specifically, the Exchange proposes that it will place Users seeking new cages on a waitlist: (1) The order of Users on the list will be based on the date the Exchange receives signed orders for the cages from each User; (2) once the list is established, Users, on a rolling basis, will be allocated a cage each time one becomes available; (3) if a cage becomes available and the User that is at the top of the waitlist turns it down because it requested a different size, that User will remain on the waitlist and the cage will be offered to the next User on the list, in order, until a User accepts it; (4) a User that turns down a cage that is the size that it requested will be removed from the waitlist; and (5) if a User requests two cages, that User will be moved to the bottom of the waitlist upon the receipt of its first cage.[17]

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 34–77304 (March 7, 2016), 81 FR 12981 ("Notice"). Amendment No.1 was included in the Notice and provided certain clarifications, including that that the proposed waiver of fees for two bundles of 24 cross connects, applicable while a User is on the waitlist, would only apply to cross-connects used to connect an individual User's non-contiguous cabinets.

[4] For purposes of the Exchange's co-location services, a "User" means any market participant that requests to receive co-location services directly from the Exchange. The Exchange provides co-location services to Users from its data center ("Data Center") in Mahwah, New Jersey.

[5] *See* Notice, 81 FR at 12981.

[6] *See id.*

[7] *See* Notice, 81 FR at 12982. A User must have at least two cabinets in the Data Center to purchase a cage. *See id.*

[8] *See* Notice, 81 FR at 12982.

[9] *See id.*

[10] *See id.*

[11] *See id.*

[12] *See id.*

[13] *See* Notice, 81 FR at 12982; *see also* Securities Exchange Act Release No. 76269 (October 26, 2015), 80 FR 66947 (October 30, 2015) (SR–NYSE–2015–42); Securities Exchange Act Release No. 76268 (October 26, 2015), 80 FR 66944 (October 30, 2015) (SR–NYSEMKT–2015–70); Securities Exchange Act Release No. 76270 (October 26, 2015), 80 FR 66944 (October 30, 2015) (SR–NYSEArca–2015–85) (collectively "Migration Filing").

[14] *See* Notice, 81 FR at 12982; *see also* Migration Filing *supra* note 13.

[15] *See* Notice, 81 FR at 12982.

In connection with the proposed waitlist procedures, the Exchange further proposes to add General Note 3 to the Price List and Fee Schedule,[18] to provide that the Exchange would, subject to specified conditions, waive the initial and monthly fee for two bundles of 24 cross connects between a User's non-contiguous cabinets while it is on the waitlist.[19] Specifically, the initial and monthly charge for two bundles of 24 cross connects will be waived for a User that is waitlisted for a cage for the duration of the waitlist period, provided that the cross connects may only be used to connect the User's non-contiguous cabinets.[20] The charge will no longer be waived once a User is removed from the waitlist.[21] In addition, a User that is removed from the waitlist but subsequently requests a cage will be added back to the bottom of the waitlist, provided that, if the User was removed from the waitlist because it turned down a cage that is the size that it requested, it will not receive a second waiver of the charge.[22]

Visitor Security Escorts

The Exchange also proposes to amend its visitor security escort fee. Currently, a User visiting its cabinet(s) in the Data Center is required to pay a $75/hour fee for a security escort.[23] The Exchange proposes to eliminate this fee for Users visiting their own cage in the Data Center,[24] and change the fee for those not visiting their own cage from $75/hour to $75/visit.[25] The Exchange states that a security escort is not needed when a User visits its own cage because that User would have access only to its own cabinets locked within its own cage,[26] and that User will not have access to the cabinets of other Users or Exchange equipment, which are locked as well.[27]

III. Discussion and Commission Findings

After careful review and consideration of the Exchange's proposal, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[28] In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(4) of the Act,[29] which requires that the rules of a national securities exchange provide for the equitable allocation of reasonable dues, fees and other charges among its members and issuers and other persons using its facilities, and with Section 6(b)(5) of the Act,[30] which requires, among other things, that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest, and not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission believes that the proposed procedures for the allocation of cages to its co-located Users and associated waiver of fees subject to specified conditions are consistent with Sections 6(b)(4) and 6(b)(5) of the Act. In particular, the Commission believes that the proposed cage allocation and waitlist procedures are reasonably designed to assist the Exchange in offering cages to current and future Users in the Data Center on terms that are equitable and not unfairly discriminatory in the event that available open contiguous space in the Data Center is not sufficient to house a newly requested cage or sufficiently limited that the Exchange cannot both provide new cages and satisfy all User demand for other co-location services. The Commission further believes that the proposal to waive the initial and monthly fee for two bundles of 24 cross connects between a User's non-contiguous cabinets while a User is on the waitlist is consistent with the Act. Users can qualify for the fee waiver by requesting a cage and being placed on the waitlist until a cage becomes available to them. Once the Exchange offers the requested size cage to a User through the allocation procedure or when a User is removed from the waitlist, the fee would no longer be waived. In addition, if a User was removed from the waitlist because it turned down a cage that was the size that it requested, it would not receive a second waiver of the charge. The Commission believes that the proposed fee waiver and associated conditions are reasonably designed to alleviate the inconvenience for waitlisted Users of having cabinets in non-contiguous spaces by removing the cost that those Users would otherwise avoid if a cage were available.

The Commission also finds the proposed amendments to the visitor security escort fee consistent with Sections 6(b)(4) and 6(b)(5) of the Act. The Exchange represents that a security escort is not needed when a User visits its own cage because that User would have access only to its own cabinets locked within its own cage,[31] and will not have access to the cabinets of other Users or Exchange equipment, which are locked as well.[32] In addition, the proposed rate of $75/visit for the visitor security escort would be a fee reduction for any visit that lasted more than an hour, and so it would reduce the burden placed on Users that remain subject to the fee. Therefore, the Commission finds the proposed amendments to the visitor security escort fee to be reasonable, equitable, and not unfairly discriminatory.

For the foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the Act.

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[16] *See id.*

[17] *See id.*

[18] *See* Notice, 81 FR at 12983.

[19] *See id.*

[20] *See id.*

[21] As noted above, a User that turns down a cage because it is not the correct size will remain on the waitlist. A User that requests to be removed or that turns down a cage that is the size that it requested will be removed from the waitlist. *See supra* note 17 and accompanying text.

[22] *See* Notice, 81 FR at 12983.

[23] *See id.*

[24] *See id.* The Exchange is also making a technical change to the fee schedule visitor fee to add clarity. *See id.*

[25] *See id.* The Exchange stated that many of the escorted visits lasted an hour or less. *See id.*

[26] *See id.*

[27] *See id.*

[28] In approving this proposed rule change, as modified by Amendment No. 1, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[29] 15 U.S.C. 78f(b)(4).

[30] 15 U.S.C. 78f(b)(5).

[31] *See supra* notes 26–27 and accompanying text.

[32] *See id.*

VII. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[33] that the proposed rule change, as modified by Amendment No.1, (File No. SR–NYSEMKT–2016–17) be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[34]

Brent J. Fields,

Secretary.

[FR Doc. 2016–09723 Filed 4–26–16; 8:45 am]

BILLING CODE 8011–01–P

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[33] 15 U.S.C. 78s(b)(2).

[34] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77676; File No. SR–NYSEMKT–2016–31]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Designation of Longer Period for Commission Action on Proposed Rule Change Amending Rule 123C–Equities To Provide for How the Exchange Would Determine an Official Closing Price if the Exchange Is Unable To Conduct a Closing Transaction

April 21, 2016.

On February 25, 2016, New York Stock Exchange LLC ("NYSE" or the "Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend Rule 123C—Equities to provide for how the Exchange would determine an Official Closing Price if the Exchange is unable to conduct a closing transaction. The proposed rule change was published for comment in the **Federal Register** on March 11, 2016.[3] The Commission has received no comment letters on the proposal.[4]

Section 19(b)(2) of the Act[5] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day for this filing is April 25, 2016.

The Commission is extending the 45-day time period for Commission action on the proposed rule change. The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider and take action on the Exchange's proposed rule change.

Accordingly, pursuant to section 19(b)(2)(A)(ii)(I) of the Act[6] and for the reasons stated above, the Commission designates June 9, 2016, as the date by which the Commission should either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NYSEMKT–2016–31).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Brent J. Fields,

Secretary.

[FR Doc. 2016–09719 Filed 4–26–16; 8:45 am]

BILLING CODE 8011–01–P

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 77306 (March 7, 2016), 81 FR 12986.

[4] The Commission notes that a comment letter was received on a nearly identical filing for New York Stock Exchange LLC and a similar filing for The Nasdaq Stock Market LLC. *See* Letter from Theodore R. Lazo, Managing Director and Associate General Counsel, Securities Industry and Financial Markets Association, to Brent J. Fields, Secretary, Commission, dated April 5, 2016. *See also* Securities Exchange Act Release Nos. 77305 (March 7, 2016), 81 FR 12977 (March 11, 2016) (SR–NYSE–2016–18) and 77309 (March 7, 2016), 81 FR 13007 (March 11, 2016) (SR–NASDAQ–2016–035).

[5] 15 U.S.C. 78s(b)(2).

[6] 15 U.S.C. 78s(b)(2)(A)(ii)(I).

[7] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77677; File No. SR–NYSE–2016–18]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Designation of Longer Period for Commission Action on Proposed Rule Change Amending Rule 123C To Provide for How the Exchange Would Determine an Official Closing Price if the Exchange Is Unable To Conduct a Closing Transaction

April 21, 2016.

On February 25, 2016, New York Stock Exchange LLC ("NYSE" or the "Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend Rule 123C to provide for how the Exchange would determine an Official Closing Price if the Exchange is unable to conduct a closing transaction. The proposed rule change was published for comment in the **Federal Register** on March 11, 2016.[3] The Commission has received one comment letter on the proposal.[4]

Section 19(b)(2) of the Act[5] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day for this filing is April 25, 2016.

The Commission is extending the 45-day time period for Commission action on the proposed rule change. The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider and take action on the Exchange's proposed rule change.

Accordingly, pursuant to section 19(b)(2)(A)(ii)(I) of the Act[6] and for the reasons stated above, the Commission designates June 9, 2016, as the date by which the Commission should either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NYSE–2016–18).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Brent J. Fields,

Secretary.

[FR Doc. 2016–09720 Filed 4–26–16; 8:45 am]

BILLING CODE 8011–01–P

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 77305 (March 7, 2016), 81 FR 12977.

[4] *See* Letter from Theodore R. Lazo, Managing Director and Associate General Counsel, Securities Industry and Financial Markets Association, to Brent J. Fields, Secretary, Commission, dated April 5, 2016.

[5] 15 U.S.C. 78s(b)(2).

[6] 15 U.S.C. 78s(b)(2)(A)(ii)(I).

[7] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77679; File No. 4–631]

Joint Industry Plan; Order Approving the Tenth Amendment to the National Market System Plan to Address Extraordinary Market Volatility by Bats BZX Exchange, Inc., Bats BYX Exchange, Inc., Chicago Stock Exchange, Inc., Bats EDGA Exchange, Inc., Bats EDGX Exchange, Inc., Financial Industry Regulatory Authority, Inc., NASDAQ BX, Inc., NASDAQ PHLX LLC, The Nasdaq Stock Market LLC, National Stock Exchange, Inc., New York Stock Exchange LLC, NYSE MKT LLC, and NYSE Arca, Inc.

April 21, 2016.

I. Introduction

On February 19, 2016, Nasdaq, Inc., on behalf of the other parties [1] to the National Market System Plan to Address Extraordinary Market Volatility (the "Plan"), filed with the Securities and Exchange Commission ("Commission") pursuant to Section 11A of the Securities Exchange Act of 1934 ("Act") [2] and Rule 608 thereunder,[3] a proposal to amend the Plan.[4] The proposal represents the tenth amendment to the Plan, and reflects proposed changes unanimously approved by the Participants ("Tenth Amendment"). The proposed Tenth Amendment was published for comment in the **Federal Register** on February 29, 2016.[5] The Commission received no comment letters regarding the amendment. This order approves the Tenth Amendment to the Plan.

II. Description of the Proposal

In the Tenth Amendment, the Participants propose to extend the pilot period of the Plan from April 22, 2016 to April 21, 2017 and make one modification to improve the operation of the Plan. Specifically, the Participants propose to modify the definition of Opening Price [6] in cases where the Primary Listing Exchange opens with quotations. Currently, the Opening Price for NMS Stocks that open on the Primary Listing Exchange with quotations is defined to be the midpoint of those quotations. The Participants propose to modify the definition of Opening Price in these circumstances to be the closing price of the NMS Stock on the Primary Listing Exchange on the previous trading day, or if no such closing price exists, the last sale on the Primary Listing Exchange reported by the SIP. The Opening Price is used under the Plan to determine the first Reference Price of the day.[7]

III. Discussion and Commission Findings

The Commission finds that the Tenth Amendment is consistent with the requirements of the Act and the rules and regulations thereunder. Specifically, the Commission finds that the Tenth Amendment is consistent with Section 11A of the Act [8] and Rule 608 thereunder [9] in that it is appropriate in the public interest, for the protection of investors and the maintenance of fair and orderly markets, and that it removes impediments to, and perfects the mechanism of, a national market system.

The Participants presented data in the Transmittal Letter and the Supplemental Joint Assessment [10] that shows that use of the Primary Listing Exchange's midpoint of the bid and ask often results in what the Participants believe is a skewed initial Reference Price.[11] The Participants also presented data that showed that most Trading Pauses occurred in securities that did not trade at or near the time of a Trading Pause (*i.e.,* those securities that opened on the midpoint of the bid and ask on the Primary Listing Exchange).[12] The Participants performed a back-testing analysis to determine the impact on Trading Pauses if the first Reference Price for the day was determined by using the Primary Listing Exchange's closing price instead of the midpoint of the Exchange's bid and ask.[13]

Based on their data, the Participants found that the majority of Trading Pauses could have been avoided if the previous day's closing price was used as the first Reference Price rather than the midpoint of the bid and ask for stocks that opened without transactions.[14] Therefore, the Participants recommend modifying the Plan to amend the definition of Opening Price so that the first Reference Price when there is no opening transaction is the Primary Listing Exchange's previous day's closing price.

The Commission believes that it is appropriate in the public interest, for the protection of investors and the maintenance of a fair and orderly market to approve the amendment to modify the definition of Opening Price. The Commission believes that the modification of the Opening Price definition is appropriate to potentially prevent Trading Pauses that are not indicative of extraordinary volatility.[15]

The Participants also propose to amend Section VIII(C) of the Plan to extend the pilot period through April 21, 2017. The Commission believes that it is appropriate in the public interest, for the protection of investors and the maintenance of a fair and orderly market to approve the amendment to extend the pilot period until April 21, 2017 because it will allow the Participants to conduct, and the Commission to consider, further analysis of data, including data related to the impact of the revised definition of Opening Price, regarding the operation of the Plan. An extension of the pilot period also will allow the Participants to finalize and file with the Commission any proposed amendments to the Plan resulting from such further analysis.

The Commission understands the Participants are conducting additional review of certain aspects of the operation of the Plan and expects that the Participants will provide additional recommendations, as necessary, relating to: (i) The harmonization of current clearly erroneous execution rules with the Plan, such that clearly erroneous execution rules could not be used to break trades occurring within the Price Bands absent a legitimate technical failure at a Self-Regulatory Organization; (ii) a review of exchange-traded products (ETPs), to determine whether adjustments should be made to the Plan to account for the particular trading characteristics of ETPs; (iii) a review of other issues with the operation of the Plan that may have been revealed by the events of August 24, 2015, including the impact of double-wide Price Bands during the opening period, and the advisability of coordinated reopening procedures; and (iv) potential enhancements to the categorization of securities into different tiers. An extension of the pilot period of the Plan will allow the Participants' ongoing review and analysis to take place and inform any subsequent amendments to the Plan. The Commission believes that a one-year extension of the Pilot will provide the Participants with sufficient time to analyze the impact of change to the definition of Opening Price on the Plan's operation, as well as complete analyses of the other outstanding matters described above.

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[1] Nasdaq, Inc. filed on behalf of the following parties to the Plan: Bats BZX Exchange, Inc., Bats BYX Exchange, Inc., Chicago Stock Exchange, Inc., Bats EDGA Exchange, Inc., Bats EDGX Exchange, Inc., Financial Industry Regulatory Authority, Inc., NASDAQ BX, Inc., NASDAQ PHLX LLC, the Nasdaq Stock Market LLC, National Stock Exchange, Inc., the New York Stock Exchange LLC, NYSE MKT LLC, and NYSE Arca, Inc. (collectively, the "Participants").

[2] 15 U.S.C. 78k–1.

[3] 17 CFR 242.608.

[4] *See* Letter from Paul Roland, Principal, U.S. Equities, Nasdaq, to Brent Fields, Secretary, Commission, dated February 18, 2016. ("Transmittal Letter").

[5] *See* Securities Exchange Act Release No. 77205 (February 22, 2016), 81 FR 10315 ("Notice").

[6] Unless otherwise specified, the terms used herein have the same meaning as set forth in the Plan.

[7] Section V(B)(1) of the Plan provides that the first Reference Price for a Trading Day shall be the Opening Price on the Primary Listing Exchange in an NMS Stock if such Opening Price occurs less than five minutes after the start of Regular Trading Hours.

[8] 15 U.S.C. 78k–1.

[9] 17 CFR 242.608.

[10] On May 28, 2015, the Participants submitted a Supplemental Joint Assessment, as required under the Plan. The Supplemental Joint Assessment is available on the SEC Web site at *http://www.sec.gov/comments/4-631/4631-39.pdf.* Under the Plan, the Participants were required to provide the Commission with a joint assessment relating to the impact of the Plan and the calibration of the Percentage Parameters by assessing certain identified areas. *See* Appendix B.III.

[11] *See* Transmittal Letter, *supra* note 4 and Notice, *supra* note 5, at Chart 1, Table 9, Table 11, Table 12, and Table 13. *See also* Supplemental Joint Assessment Section V.

[12] *Id.* at Table 9, Table 11, Table 12, and Table 13.

[13] *Id.* at Table 10, Table 11, Table 12, and Table 13.

[14] *See* Transmittal Letter, *supra* note 4 and Notice, *supra* note 5.

[15] Consistent with their representations set forth in the Notice, the Commission expects the Participants to implement the amendment to the definition of Opening Price within three months of the date of this order.

For the reasons noted above, the Commission finds that the Tenth Amendment to the Plan is consistent with Section 11A of the Act[16] and Rule 608 thereunder.[17] The Commission reiterates its expectation that the Participants will continue to monitor the scope and operation of the Plan and study the data produced, and will propose any modifications to the Plan that may be necessary or appropriate.[18]

IV. Conclusion

It is therefore ordered, pursuant to Section 11A of the Act[19] and Rule 608 thereunder,[20] that the Tenth Amendment to the Plan (File No. 4–631) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Brent J. Fields,

Secretary.

[FR Doc. 2016–09722 Filed 4–26–16; 8:45 am]

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[16] 15 U.S.C. 78k–1.

[17] 17 CFR 242.608.

[18] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012).

[19] 15 U.S.C. 78k–1.

[20] 17 CFR 242.608.

[21] 17 CFR 200.30–3(a)(29).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77678; File No. SR–NASDAQ–2016–035]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Designation of Longer Period for Commission Action on Proposed Rule Change To Establish a Secondary Contingency Procedure To Enable the Exchange To Report an Official Closing Price on Behalf of an Impaired Primary Listing Exchange

April 21, 2016.

On March 2, 2016, The Nasdaq Stock Market LLC ("Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change to establish a Secondary Contingency Procedure for its closing cross. The proposed rule change was published for comment in the **Federal Register** on March 11, 2016.[3] The Commission has received one comment letter on the proposal.[4]

Section 19(b)(2) of the Act[5] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day for this filing is April 25, 2016.

The Commission is extending the 45-day time period for Commission action on the proposed rule change. The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change.

Accordingly, pursuant to Section 19(b)(2) of the Act[6] and for the reasons stated above, the Commission designates June 9, 2016, as the date by which the Commission should either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NASDAQ–2016–035).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Brent J. Fields,

Secretary.

[FR Doc. 2016–09721 Filed 4–26–16; 8:45 am]

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 77309 (March 7, 2016), 81 FR 13007.

[4] *See* Letter from Theodore R. Lazo, Managing Director and Associate General Counsel, Securities Industry and Financial Markets Association, to Brent J. Fields, Secretary, Commission, dated April 5, 2016.

[5] 15 U.S.C. 78s(b)(2).

[6] 15 U.S.C. 78s(b)(2).

[7] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77673; File No. SR–Phlx–2016–51]

Self-Regulatory Organizations; NASDAQ PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Qualified Contingent Cross Pricing

April 21, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1], and Rule 19b–4 thereunder,[2] notice is hereby given that on April 14, 2016, NASDAQ PHLX LLC ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's Pricing Schedule at Section II, entitled "Multiply Listed Options Fees." Specifically, the Exchange is proposing to amend the Qualified Contingent Cross ("QCC") pricing.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqomxphlx.cchwallstreet.com/*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Exchange's Pricing Schedule at Section II, entitled "Multiply Listed Options Fees." Specifically, the Exchange is proposing to amend QCC pricing.

QCC Transaction Fee

Today, the Exchange assesses a QCC Transaction Fee of $0.20 per contract to a Specialist,[3] Market Maker,[4] Professional,[5] Firm[6] and Broker-Dealer.[7] Customers are not assessed a QCC Transaction Fee. The Exchange proposes to no longer assess Professionals a QCC Transaction Fee.

QCC Rebate

The Exchange also pays rebates on QCC Orders.[8] Rebates are paid for all qualifying executed QCC Orders, as defined in Rule 1080(o)[9] and Floor QCC Orders, as defined in Rule 1064(e),[10] except where the transaction is either: (i) Customer-to-Customer; or (ii) a dividend, merger, short stock interest or reversal or conversion strategy execution.[11] The maximum QCC Rebate to be paid in a given month will not exceed $450,000.[12] The Exchange pays rebates to market participants acting as agent on qualifying QCC Orders. The Exchange proposes to no longer pay QCC Rebates on Customer-to-Professional orders.[13]

QCC Orders are an order to buy or sell at least 1,000 contracts, or 10,000 contracts in the case of Mini Options.[14] These large-sized contingent orders are complex in nature and have a stock-tied component, which requires the option leg to be executed at the NBBO or better. The parties to a contingent trade are focused on the spread or ratio between the transaction prices for each of the component instruments (*i.e.*, the net price of the entire contingent trade), rather than on the absolute price of any single component. Permitting Professional orders to be treated similar to Customer orders with respect to this order type is reasonable because of the characteristics of the QCC Order which are described above.

The differentiation between a Customer and Professional is not necessary with respect to QCC Orders because these orders are exempt from requirements regarding order exposure.[15] Further, QCC Orders are not executed pursuant to a priority scheme.[16] Also, as explained above, because of the size of the order, sophistication of the investor and complexity of the transaction, it is difficult to distinguish as between a Customer and Professional with respect to QCC Orders.[17]

Finally, the Exchange believes that treating Customer orders and Professional orders in a similar manner with respect to fees, when transacting QCC Orders, will attract more QCC Orders to the Exchange because there would be no fee for Professional orders.

2. Statutory Basis

The proposal is consistent with Section 6(b) of the Act,[18] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[19] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which the Exchange operates or controls, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system "has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies." [20]

Likewise, in *NetCoalition* v. *Securities and Exchange Commission* ("NetCoalition") [21] the D.C. Circuit upheld the Commission's use of a market-based approach in evaluating the fairness of market data fees against a challenge claiming that Congress mandated a cost-based approach.[22] As the court emphasized, the Commission "intended in Regulation NMS that 'market forces, rather than regulatory requirements' play a role in determining the market data . . . to be made available to investors and at what cost." [23]

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[3] A "Specialist" is an Exchange member who is registered as an options specialist pursuant to Rule 1020(a).

[4] The term "Market Maker" includes Registered Options Traders ("ROT"). *See* Exchange Rule 1014(b)(i) and (ii). A ROT includes a Streaming Quote Trader or "SQT," a Remote Streaming Quote Trader or "RSQT" and a Non-SQT, which by definition is neither a SQT nor a RSQT. A ROT is defined in Exchange Rule 1014(b) as a regular member or a foreign currency options participant of the Exchange located on the trading floor who has received permission from the Exchange to trade in options for his own account. An SQT is an ROT who has received permission from the Exchange to generate and submit option quotations electronically in options to which such SQT is assigned. *See* Rule 1014(b)(ii)(A). An RSQT is an ROT that is a member affiliated with and Remote Streaming Quote Organization with no physical trading floor presence who has received permission from the Exchange to generate and submit option quotations electronically in options to which such RSQT has been assigned. *See* Rule 1014(b)(ii)(B).

[5] The term "Professional" means any person or entity that (i) is not a broker or dealer in securities, and (ii) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). *See* Rule 1000(b)(14).

[6] The term "Firm" applies to any transaction that is identified by a member or member organization for clearing in the Firm range at The Options Clearing Corporation.

[7] The term "Broker-Dealer" applies to any transaction which is not subject to any of the other transaction fees applicable within a particular category.

[8] *See* Section II of the Pricing Schedule.

[9] A QCC Order is comprised of an originating order to buy or sell at least 1,000 contracts, or 10,000 contracts in the case of Mini Options, that is identified as being part of a qualified contingent trade, as that term is defined in Rule 1080(o)(3), coupled with a contra-side order or orders totaling an equal number of contracts. *See* Rule 1080(o).

[10] A Floor QCC Order must: (i) Be for at least 1,000 contracts; (ii) meet the six requirements of Rule 1080(o)(3) which are modeled on the QCT Exemption; (iii) be executed at a price at or between the National Best Bid and Offer ("NBBO"); and (iv) be rejected if a Customer order is resting on the Exchange book at the same price. In order to satisfy the 1,000-contract requirement, a Floor QCC Order must be for 1,000 contracts and could not be, for example, two 500-contract orders or two 500-contract legs.

[11] *See* Section II of the Pricing Schedule.

[12] *Id.*

[13] At this time, the Exchange will continue to pay a QCC Rebate where the transaction is Professional-to-Professional.

[14] *See* notes 9 and 10 above.

[15] *See* Rule 1080(c)(ii)(C).

[16] By way of comparison, Customers receive priority over other market participants with respect to the execution of their order within the Exchange's order book or on the Floor.

[17] A Professional transacting a QCC Order would count that order toward the 390 orders in listed options per day. *See* note 5 above.

[18] 15 U.S.C. 78f(b).

[19] 15 U.S.C. 78f(b)(4) and (5).

[20] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37497, 37499 (June 29, 2005) ("Regulation NMS Adopting Release").

[21] *See* Securities Exchange Act Release No. 51808 (June 9, 2005) at 534–535.

[22] *See* Securities Exchange Act Release No. 51808 (June 9, 2005) at 534.

[23] *See* Securities Exchange Act Release No. 51808 (June 9, 2005) at 537.

Further, "[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers' . . . ." [24] Although the court and the SEC were discussing the cash equities markets, the Exchange believes that these views apply with equal force to the options markets.

It is reasonable to no longer assess a QCC Transaction Fee for Professional orders and to not pay a QCC Rebate on Customer-to-Professional orders because the distinction that necessitated the differentiation as between Customer and Professional orders is not meaningful with respect to QCC Orders. QCC Orders are orders to buy or sell at least 1,000 contracts, or 10,000 contracts in the case of Mini Options.[25] These large-sized contingent orders are complex in nature and have a stock-tied component, which requires the option leg to be executed at the NBBO or better. The parties to a contingent trade are focused on the spread or ratio between the transaction prices for each of the component instruments (*i.e.*, the net price of the entire contingent trade), rather than on the absolute price of any single component. Also, no Customer priority exists with respect to QCC Orders as with orders transacted within the order book or on the Floor. Permitting Professional orders to be treated similar to Customer orders with respect to this order type will attract more QCC Orders to the Exchange because the Exchange would no longer assess a QCC Transaction Fee for Professional orders.

Further, the Exchange recently amended its definition of a Professional to add specificity with respect to the manner in which the volume threshold will be calculated to determine if orders should be treated as Professional.[26] Currently, member organizations are required to review their Customers' activity on at least a quarterly basis to determine whether orders that are not for the account of a broker-dealer should be represented as Customer orders or Professional orders.[27] The Exchange anticipates that the specificity added to the Professional definition may cause current market participants that mark orders as Customer to be required to mark those orders as Professional as the calendar quarter comes to a close. Orders that were marked Customer were not subject to a fee. With this proposal, Professional orders would not be assessed a QCC Transaction Fee. Furthermore, when a QCC Order is Customer-to-Customer or Customer-to-Professional the agent transacting the QCC Order will not be eligible to receive a QCC Rebate.

The Exchange believes that no longer assessing a QCC Transaction Fee for Professional orders and not paying a QCC Rebate on Customer-to-Professional orders is equitable and not unfairly discriminatory because QCC Orders are distinctive as compared to transactions executed within the order book or on the Floor, which orders are subject to exposure and grant Customers priority over other market participants. The original purpose for the distinction between a Customer and a Professional was to prevent market professionals [28] with access to sophisticated trading systems that contain functionality not available to retail Customers, from taking advantage of Customer priority, where Customer orders are given execution priority over non-Customer orders. The Exchange noted at the time that it adopted the Professional designation that identifying Professional accounts based upon the average number of orders entered for a beneficial account was an appropriate objective approach that would reasonably distinguish such persons and entities from retail investors.[29] QCC Orders are by definition large-sized contingent orders which have a stock-tied component.

With respect to QCC transactions, the Commission noted in an order approving a qualified contingent cross order type on International Securities Exchange, LLC ("ISE") that "The Commission believes that those customers participating in QCC Orders will likely be sophisticated investors who should understand that, without a requirement of exposure for QCC Orders, their order would not be given an opportunity for price improvement on the Exchange. These customers should be able to assess whether the net prices they are receiving for their QCC Order are competitive, and who will have the ability to choose among broker-dealers if they believe the net price one broker-dealer provides is not competitive. Further, broker-dealers are subject to a duty of best execution for their customers' orders, and that duty does not change for QCC Orders." [30] The intent behind the Professional designation does not apply in the context of transacting QCC Orders, because of the size of the order, sophistication of the investor and complexity of the transaction, and therefore the pricing differentiation is not necessary. For these reasons the Exchange believes that distinguishing a Customer order from a Professional order is not necessary with respect to QCC Orders.

With respect to distinguishing Professional orders from other Non-Customer participant orders, the Exchange notes that these other market participants are distinct from a Professional for purposes of assessing QCC Transaction fees for the below reasons. With respect to Firms, these market participants are eligible for the Monthly Firm Fee Cap of $75,000 per month.[31] Firms are not subject to QCC Transaction Fees once the Monthly Firm Fee Cap is met in a given month. Specialists and Market Makers are eligible for the Monthly Market Maker

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[24] *See* Securities Exchange Act Release No. 51808 (June 9, 2005) at 539 (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21).

[25] *See* notes 9 and 10 above.

[26] *See* Securities Exchange Act Release No. 77054 (February 4, 2016), 81 FR 7166 (February 10, 2016) (SR–Phlx–2016–10) (Notice of Filing of Proposed Rule Change Relating to Professional Customer Definition). This rule change became operative on April 1, 2016.

[27] Orders for any Customer that had an average of more than 390 orders per day during any month of a calendar quarter must be represented as Professional orders for the next calendar quarter. Member organizations are required to conduct a quarterly review and make any appropriate changes to the way in which they are representing orders within five days after the end of each calendar quarter. While member organizations will only be required to review their accounts on a quarterly basis, if during a quarter the Exchange identifies a Customer for which orders are being represented as Customer orders but that has averaged more than 390 orders per day during a month, the Exchange will notify the member organization and the member organization will be required to change the manner in which it is representing the Customer's orders within five days. *See Id.* at 7165, n.5.

[28] The Exchange noted in its filing that market professionals have access to functionality, including things such as continuously updated pricing models based upon real-time streaming data, access to multiple markets simultaneously and order and risk management tools. *See* Securities and Exchange Act Release No. 61426 (January 26, 2010), 75 FR 5360 (February 2, 2010) (SR–Phlx–2010–05).

[29] *See* Securities and Exchange Act Release No. 61426 (January 26, 2010), 75 FR 5360 (February 2, 2010) (SR–Phlx–2010–05).

[30] *See* Securities and Exchange Act Release No. 63955 (February 24, 2011), 76 FR 11533 (March 2, 2011) (SR–ISE–2010–73).

[31] Firms are subject to a maximum fee of $75,000 ("Monthly Firm Fee Cap"). Firm Floor Option Transaction Charges and QCC Transaction Fees, in the aggregate, for one billing month will not exceed the Monthly Firm Fee Cap per member organization when such members are trading in their own proprietary account. *See* Section II of the Pricing Schedule.

Cap of $500,000 per month.[32] Specialists and Market Makers are not subject to QCC Transaction Fees once the Monthly Market Maker Cap is met in a given month. Professionals are not subject to similar caps. With respect to Broker-Dealers, the Exchange notes that members may choose to register as a Broker-Dealer. This category of market participant transacts QCC Orders on an agency basis and receives eligible rebates pursuant to the QCC Rebate Schedule.[33] By way of example, presume a Customer order to buy 10,000 contracts eligible as a QCC Order. Presume the selling contra-parties to this order are a Customer, Professional, Firm, Specialist and Broker-Dealer each with 2,000 contracts. In this example, the Customer buying order will not be subject to a QCC Transaction Fee. The Customer selling order would not be subject to a fee or rebate. The Professional selling order would not be subject to a fee or rebate as proposed herein. Orders for Firms, Specialists and Broker-Dealers would be assessed a $0.20 per contract QCC Transaction Fee and would be eligible for rebates pursuant to the QCC Rebate Schedule. Market participants acting as agent, as compared to market participants trading for their own account, are eligible to receive QCC Rebates. The Exchange pays QCC Rebates to market participants acting as agent for QCC Orders, subject to the QCC Rebate Schedule.

The Exchange believes that distinguishing Professional orders from other Non-Customer orders is equitable and not unfairly discriminatory because with respect to QCC Orders it is difficult to distinguish a Customer order from a Professional order. QCC Orders are an exception to the general distinctions drawn as between Customer orders and Professional orders. Aside from the lack of priority for QCC Orders, the size of the order, sophistication of the investor and complexity of the transaction make it difficult to distinguish a Customer order from a Professional order. For purposes of the QCC Order, the Exchange believes that such distinction is not necessary.

Further, the Exchange's proposal would continue to assess all other market participants a QCC Transaction Fee of $0.20 per contract. Also, Customer-to-Professional orders will not be eligible for a QCC Rebate for the reasons explained herein.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. In terms of inter-market competition, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

The initial purpose of the distinction between a Customer order and a Professional order was to prevent market professionals with access to sophisticated trading systems that contain functionality not available to retail customers, from taking advantage of Customer priority, where Customer orders are given execution priority over Non-Customer orders. Professional orders are identified based upon the average number of orders entered for a beneficial account.[34]

QCC Orders are by definition large-sized contingent orders which have a stock-tied component. The parties to a contingent trade are focused on the spread or ratio between the transaction prices for each of the component instruments (*i.e.*, the net price of the entire contingent trade), rather than on the absolute price of any single component. Treating Customer orders and Professional orders in the same manner in terms of pricing with respect to QCC Orders does not provide any advantage to a Professional. The distinction does not create an opportunity to burden competition, for the reasons stated herein with respect to priority as well as the reasons below.

With respect to distinguishing Professional orders from other Non-Customer orders, the Exchange notes that Non-Customer orders are distinct from Professional orders for purposes of assessing QCC Transaction fees. Firms are eligible for the Monthly Firm Fee Cap and not subject to QCC Transaction Fees once the Monthly Firm Fee Cap is met in a given month.[35] Specialists and Market Makers are eligible for the Monthly Market Maker Cap and not subject to QCC Transaction Fees once the Monthly Market Maker Cap is met in a given month.[36] Professionals are not subject to similar caps. With respect to Broker-Dealers, the Exchange notes that members may choose to register as a Broker-Dealer. This category of market participant transacts QCC Orders on an agency basis and is eligible to receive QCC Rebates. Further, the Exchange's proposal would continue to assess Specialist, Marker Maker, Firm and Broker-Dealer orders similar to QCC Transaction Fee of $0.20 per contract. Also, Customer-to-Professional orders do not impose an undue burden on intra-market competition for the reasons explained herein.

The Exchange's proposal does not place on undue burden on inter-market competition because the QCC order type is similar on other options exchanges[37] and these exchanges may also file to eliminate the distinction between Customers and Professionals for the QCC order type.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[38]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

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[32] Specialists and Market Makers are subject to a "Monthly Market Maker Cap" of $500,000 for: (i) Electronic Option Transaction Charges; and (ii) QCC Transaction Fees (as defined in Exchange Rule 1080(o) and Floor QCC Orders, as defined in 1064(e)). The trading activity of separate Specialist and Market Maker member organizations will be aggregated in calculating the Monthly Market Maker Cap if there is Common Ownership between the member organizations. *See* Section II of the Pricing Schedule.

[33] QCC Rebates are paid by volume. There are currently six tiers which pay a QCC Rebate between $0.00 and $0.11 per contract. *See* Section II of the Pricing Schedule. Of note, market participants may transact QCC Orders on an agency basis and be eligible for a QCC Rebate.

[34] *See* note 5.

[35] Market participants acting as agents would be eligible to receive a QCC Rebate.

[36] Specialists and Market Makers trade only for their own account.

[37] *See* Chicago Board Options Exchange, Incorporated's Fees Schedule and Miami International Securities Exchange LLC's Pricing Schedule.

[38] 15 U.S.C. 78s(b)(3)(A)(ii).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2016–51 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2016–51. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*).

Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File Number SR–Phlx–2016–51 and should be submitted on or before May 18, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[39]

Brent J. Fields,

Secretary.

[FR Doc. 2016–09716 Filed 4–26–16; 8:45 am]

BILLING CODE 8011–01–P

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[39] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77682; File No. SR–NYSEARCA–2016–21]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Approving a Proposed Rule Change, as Modified by Amendment No. 1, To Establish Procedures for the Allocation of Cages to Co-Located Users, Including the Waiver of Certain Fees, and To Amend the Visitor Security Escort Fee

April 21, 2016.

I. Introduction

On February 23, 2016 NYSE Arca, Inc. ("the Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change to establish procedures for the allocation of cages to co-located Users, including the waiver of certain fees, and to amend the visitor security escort fee. On March 1, 2016, the Exchange filed Amendment No. 1 to the proposed rule change. The proposed rule change, as modified by Amendment No. 1, was published for comment in the **Federal Register** on March 11, 2016.[3] There were no comments on the proposed rule change.[4] This order approves the proposed rule change, as modified by Amendment No. 1.

II. Background and Description of the Proposal, as Modified by Amendment No. 1

The Exchange proposes to establish procedures for the allocation of cages to its co-located Users,[5] including the waiver of certain fees subject to specified conditions, and to amend the visitor security escort fee.[6] The Exchange proposes to amend the NYSE Arca Equities Schedule of Fees and Charges for Exchange Services ("Schedule of Fees") and the NYSE Arca Options Fee Schedule ("Fee Schedule") to reflect the changes.[7]

As more fully set forth in the Notice, the Exchange offers Users the ability to rent cages to house their cabinets in the Data Center,[8] and historically has offered these cages on a first come/first serve basis.[9] The Exchange states that a cage typically is purchased by a User that has several cabinets within Data Center and wishes to arrange its cabinets contiguously while also enhancing privacy around its cabinets.[10] The Exchange offers three cage sizes, corresponding to the number of cabinets housed therein, and charges fees for the cages based on the size.[11] The physical footprint of each cage is greater than that of the cabinets that it houses, as each cage is constructed so as to include aisles around the purchasing User's cabinets, for accessibility and to comply with safety regulations.[12] In order to offer the cages, the Exchange must have sufficient contiguous open space available for the cage.[13]

In 2015, the Exchange determined that to continue to be able to meet its obligation to accommodate demand, and in particular to make available more contiguous, larger spaces for new and existing Users, it would exercise its right to move some Users' equipment within the Data Center (the "Migration").[14] The Exchange established procedures to manage the Migration process, and continues to implement them.[15] The Exchange states that, notwithstanding the Migration, contiguous open space will still be limited, and may become more limited over time.[16]

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 34–77303 (March 7, 2016), 81 FR 13003 ("Notice"). Amendment No.1 was included in the Notice and provided certain clarifications, including that the proposed waiver of fees for two bundles of 24 cross connects, applicable while a User is on the waitlist, would only apply to cross-connects used to connect an individual User's non-contiguous cabinets.

[4] The Commission notes that it received one letter referencing this filing that addresses issues outside the scope of this proposal.

[5] For purposes of the Exchange's co-location services, a "User" means any market participant that requests to receive co-location services directly from the Exchange. The Exchange provides co-location services to Users from its data center ("Data Center") in Mahwah, New Jersey.

[6] *See* Notice, 81 FR at 13003.

[7] *See id.*

[8] *See id.* A User must have at least two cabinets in the Data Center to purchase a cage. *See id.*

[9] *See id.*

[10] *See id.*

[11] *See id.*

[12] *See id.*

[13] *See* Notice, 81 FR at 13003–13004.

[14] *See* Notice, 81 FR at 13004; *see also* Securities Exchange Act Release No. 76269 (October 26, 2015), 80 FR 66947 (October 30, 2015) (SR–NYSE–2015–42); Securities Exchange Act Release No. 76268 (October 26, 2015), 80 FR 66944 (October 30, 2015) (SR–NYSEMKT–2015–70); Securities Exchange Act Release No. 76270 (October 26, 2015), 80 FR 66944 (October 30, 2015) (SR–NYSEArca–2015–85) (collectively "Migration Filing").

Proposed Cage Allocation Procedure

The Exchange has proposed to establish procedures governing the allocation of cages should the currently available open contiguous space in the Data Center be insufficient to house a new cage or if the open contiguous space available is sufficiently limited such that the Exchange cannot both provide new cages and satisfy all User demand for other co-location services.[17] Specifically, the Exchange proposes that it will place Users seeking new cages on a waitlist: (1) The order of Users on the list will be based on the date the Exchange receives signed orders for the cages from each User; (2) once the list is established, Users, on a rolling basis, will be allocated a cage each time one becomes available; (3) if a cage becomes available and the User that is at the top of the waitlist turns it down because it requested a different size, that User will remain on the waitlist and the cage will be offered to the next User on the list, in order, until a User accepts it; (4) a User that turns down a cage that is the size that it requested will be removed from the waitlist; and (5) if a User requests two cages, that User will be moved to the bottom of the waitlist upon the receipt of its first cage.[18]

In connection with the proposed waitlist procedures, the Exchange further proposes to add General Note 3 to the Schedule of Fees and Fee Schedule,[19] to provide that the Exchange would, subject to specified conditions, waive the initial and monthly fee for two bundles of 24 cross connects between a User's non-contiguous cabinets while it is on the waitlist.[20] Specifically, the initial and monthly charge for two bundles of 24 cross connects will be waived for a User that is waitlisted for a cage for the duration of the waitlist period, provided that the cross connects may only be used to connect the User's non-contiguous cabinets.[21] The charge will no longer be waived once a User is removed from the waitlist.[22] In addition, a User that is removed from the waitlist but subsequently requests a cage will be added back to the bottom of the waitlist, provided that, if the User was removed from the waitlist because it turned down a cage that is the size that it requested, it will not receive a second waiver of the charge.[23]

Visitor Security Escorts

The Exchange also proposes to amend its visitor security escort fee. Currently, a User visiting its cabinet(s) in the Data Center is required to pay a $75/hour fee for a security escort.[24] The Exchange proposes to eliminate this fee for Users visiting their own cage in the Data Center,[25] and change the fee for those not visiting their own cage from $75/hour to $75/visit.[26] The Exchange states that a security escort is not needed when a User visits its own cage because that User would have access only to its own cabinets locked within its own cage,[27] and that User will not have access to the cabinets of other Users or Exchange equipment, which are locked as well.[28]

III. Discussion and Commission Findings

After careful review and consideration of the Exchange's proposal, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[29] In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(4) of the Act,[30] which requires that the rules of a national securities exchange provide for the equitable allocation of reasonable dues, fees and other charges among its members and issuers and other persons using its facilities, and with Section 6(b)(5) of the Act,[31] which requires, among other things, that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest, and not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission believes that the proposed procedures for the allocation of cages to its co-located Users and associated waiver of fees subject to specified conditions are consistent with Sections 6(b)(4) and 6(b)(5) of the Act. In particular, the Commission believes that the proposed cage allocation and waitlist procedures are reasonably designed to assist the Exchange in offering cages to current and future Users in the Data Center on terms that are equitable and not unfairly discriminatory in the event that available open contiguous space in the Data Center is not sufficient to house a newly requested cage or sufficiently limited that the Exchange cannot both provide new cages and satisfy all User demand for other co-location services. The Commission further believes that the proposal to waive the initial and monthly fee for two bundles of 24 cross connects between a User's non-contiguous cabinets while a User is on the waitlist is consistent with the Act. Users can qualify for the fee waiver by requesting a cage and being placed on the waitlist until a cage becomes available to them. Once the Exchange offers the requested size cage to a User through the allocation procedure or when a User is removed from the waitlist, the fee would no longer be waived. In addition, if a User was removed from the waitlist because it turned down a cage that was the size that it requested, it would not receive a second waiver of the charge. The Commission believes that the proposed fee waiver and associated conditions are reasonably designed to alleviate the inconvenience for waitlisted Users of having cabinets in non-contiguous spaces by removing the cost that those Users would otherwise avoid if a cage were available.

The Commission also finds the proposed amendments to the visitor security escort fee consistent with Sections 6(b)(4) and 6(b)(5) of the Act. The Exchange represents that a security escort is not needed when a User visits its own cage because that User would have access only to its own cabinets locked within its own cage,[32] and will not have access to the cabinets of other Users or Exchange equipment, which are locked as well.[33] In addition, the proposed rate of $75/visit for the visitor security escort would be a fee reduction for any visit that lasted more than an hour, and so it would reduce the burden placed on Users that remain subject to the fee. Therefore, the Commission finds the proposed amendments to the visitor security escort fee to be reasonable, equitable, and not unfairly discriminatory.

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[15] *See* Notice, 81 FR at 13004; *see also* Migration Filing *supra* note 14.

[16] *See* Notice, 81 FR at 13004.

[17] *See id.*

[18] *See id.*

[19] *See id.*

[20] *See id.*

[21] *See id.*

[22] As noted above, a User that turns down a cage because it is not the correct size will remain on the waitlist. A User that requests to be removed or that turns down a cage that is the size that it requested will be removed from the waitlist. *See supra* note 18 and accompanying text.

[23] *See* Notice, 81 FR at 13004.

[24] *See* Notice, 81 FR at 13005.

[25] *See id.* The Exchange is also making a technical change to the visitor fee on the Schedule of Fees and Fee Schedule to add clarity. *See id.*

[26] *See id.* The Exchange stated that many of the escorted visits lasted an hour or less. *See id.*

[27] *See* Notice, 81 FR at 13004.

[28] *See id.*

[29] In approving this proposed rule change, as modified by Amendment No. 1, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[30] 15 U.S.C. 78f(b)(4).

[31] 15 U.S.C. 78f(b)(5).

[32] *See supra* notes 27–28 and accompanying text.

For the foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the Act.

VII. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[34] that the proposed rule change, as modified by Amendment No.1, (File No. SR–NYSEARCA–2016–21) be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[35]

Brent J. Fields,

Secretary.

[FR Doc. 2016–09725 Filed 4–26–16; 8:45 am]

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[33] *See id.*

[34] 15 U.S.C. 78s(b)(2).

[35] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77681; File No. SR–NYSE–2016–13]

Self-Regulatory Organizations; New York Stock Exchange LLC; Order Approving a Proposed Rule Change, as Modified by Amendment No. 1, To Establish Procedures for the Allocation of Cages to Co-Located Users, Including the Waiver of Certain Fees, and To Amend the Visitor Security Escort Fee

April 21, 2016.

I. Introduction

On February 23, 2016 New York Stock Exchange LLC ("the Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change to establish procedures for the allocation of cages to co-located Users, including the waiver of certain fees, and to amend the visitor security escort fee. On March 1, 2016, the Exchange filed Amendment No. 1 to the proposed rule change. The proposed rule change, as modified by Amendment No. 1, was published for comment in the **Federal Register** on March 11, 2016.[3] There were no comments on the proposed rule change. This order approves the proposed rule change, as modified by Amendment No. 1.

II. Background and Description of the Proposal, as Modified by Amendment No. 1

The Exchange proposes to establish procedures for the allocation of cages to its co-located Users,[4] including the waiver of certain fees subject to specified conditions, and to amend the visitor security escort fee.[5] The Exchange proposes to amend its Price List ("Price List") to reflect the changes.[6]

As more fully set forth in the Notice, the Exchange offers Users the ability to rent cages to house their cabinets in the Data Center,[7] and historically has offered these cages on a first come/first serve basis.[8] The Exchange states that a cage typically is purchased by a User that has several cabinets within the Data Center and wishes to arrange its cabinets contiguously while also enhancing privacy around its cabinets.[9] The Exchange offers three cage sizes, corresponding to the number of cabinets housed therein, and charges fees for the cages based on the size.[10] The physical footprint of each cage is greater than that of the cabinets that it houses, as each cage is constructed so as to include aisles around the purchasing User's cabinets, for accessibility and to comply with safety regulations.[11] In order to offer the cages, the Exchange must have sufficient contiguous open space available for the cage.[12]

In 2015, the Exchange determined that to continue to be able to meet its obligation to accommodate demand, and in particular to make available more contiguous, larger spaces for new and existing Users, it would exercise its right to move some Users' equipment within the Data Center (the "Migration").[13] The Exchange established procedures to manage the Migration process, and continues to implement them.[14] The Exchange states that, notwithstanding the Migration, contiguous open space will still be limited, and may become more limited over time.[15]

Proposed Cage Allocation Procedure

The Exchange has proposed to establish procedures governing the allocation of cages should the currently available open contiguous space in the Data Center be insufficient to house a new cage or if the open contiguous space available is sufficiently limited such that the Exchange cannot both provide new cages and satisfy all User demand for other co-location services.[16] Specifically, the Exchange proposes that it will place Users seeking new cages on a waitlist: (1) The order of Users on the list will be based on the date the Exchange receives signed orders for the cages from each User; (2) once the list is established, Users, on a rolling basis, will be allocated a cage each time one becomes available; (3) if a cage becomes available and the User that is at the top of the waitlist turns it down because it requested a different size, that User will remain on the waitlist and the cage will be offered to the next User on the list, in order, until a User accepts it; (4) a User that turns down a cage that is the size that it requested will be removed from the waitlist; and (5) if a User requests two cages, that User will be moved to the bottom of the waitlist upon the receipt of its first cage.[17]

In connection with the proposed waitlist procedures, the Exchange further proposes to add General Note 3 to the Price List,[18] to provide that the Exchange would, subject to specified conditions, waive the initial and monthly fee for two bundles of 24 cross connects between a User's non-contiguous cabinets while it is on the waitlist.[19] Specifically, the initial and monthly charge for two bundles of 24 cross connects will be waived for a User that is waitlisted for a cage for the duration of the waitlist period, provided that the cross connects may only be used to connect the User's non-contiguous cabinets.[20] The charge will no longer be waived once a User is removed from the waitlist.[21] In addition, a User that is removed from the waitlist but subsequently requests a cage will be added back to the bottom of the waitlist, provided that, if the User was removed from the waitlist because it turned down a cage that is the size that it requested, it will not receive a second waiver of the charge.[22]

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 34–77302 (March 7, 2016), 81 FR 12998 ("Notice"). Amendment No.1 was included in the Notice and provided certain clarifications, including that the proposed waiver of fees for two bundles of 24 cross connects, applicable while a User is on the waitlist, would only apply to cross-connects used to connect an individual User's non-contiguous cabinets.

[4] For purposes of the Exchange's co-location services, a "User" means any market participant that requests to receive co-location services directly from the Exchange. The Exchange provides co-location services to Users from its data center ("Data Center") in Mahwah, New Jersey.

[5] *See* Notice, 81 FR at 12999.

[6] *See id.*

[7] *See id.* A User must have at least two cabinets in the Data Center to purchase a cage. *See id.*

[8] *See id.*

[9] *See id.*

[10] *See id.*

[11] *See id.*

[12] *See id.*

[13] *See id.; see also* Securities Exchange Act Release No. 76269 (October 26, 2015), 80 FR 66947 (October 30, 2015) (SR–NYSE–2015–42); Securities Exchange Act Release No. 76268 (October 26, 2015), 80 FR 66944 (October 30, 2015) (SR–NYSEMKT–2015–70); Securities Exchange Act Release No. 76270 (October 26, 2015), 80 FR 66944 (October 30, 2015) (SR–NYSEArca–2015–85) (collectively "Migration Filing").

[14] *See* Notice, 81 FR at 12999; *see also* Migration Filing *supra* note 13.

[15] *See* Notice, 81 FR at 12999.

[16] *See id.*

[17] *See id.*

[18] *See* Notice, 81 FR at 13000.

Visitor Security Escorts

The Exchange also proposes to amend its visitor security escort fee. Currently, a User visiting its cabinet(s) in the Data Center is required to pay a $75/hour fee for a security escort.[23] The Exchange proposes to eliminate this fee for Users visiting their own cage in the Data Center,[24] and change the fee for those not visiting their own cage from $75/hour to $75/visit.[25] The Exchange states that a security escort is not needed when a User visits its own cage because that User would have access only to its own cabinets locked within its own cage,[26] and that User will not have access to the cabinets of other Users or Exchange equipment, which are locked as well.[27]

III. Discussion and Commission Findings

After careful review and consideration of the Exchange's proposal, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[28] In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(4) of the Act,[29] which requires that the rules of a national securities exchange provide for the equitable allocation of reasonable dues, fees and other charges among its members and issuers and other persons using its facilities, and with Section 6(b)(5) of the Act,[30] which requires, among other things, that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest, and not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission believes that the proposed procedures for the allocation of cages to its co-located Users and associated waiver of fees subject to specified conditions are consistent with Sections 6(b)(4) and 6(b)(5) of the Act. In particular, the Commission believes that the proposed cage allocation and waitlist procedures are reasonably designed to assist the Exchange in offering cages to current and future Users in the Data Center on terms that are equitable and not unfairly discriminatory in the event that available open contiguous space in the Data Center is not sufficient to house a newly requested cage or sufficiently limited that the Exchange cannot both provide new cages and satisfy all User demand for other co-location services. The Commission further believes that the proposal to waive the initial and monthly fee for two bundles of 24 cross connects between a User's non-contiguous cabinets while a User is on the waitlist is consistent with the Act. Users can qualify for the fee waiver by requesting a cage and being placed on the waitlist until a cage becomes available to them. Once the Exchange offers the requested size cage to a User through the allocation procedure or when a User is removed from the waitlist, the fee would no longer be waived. In addition, if a User was removed from the waitlist because it turned down a cage that was the size that it requested, it would not receive a second waiver of the charge. The Commission believes that the proposed fee waiver and associated conditions are reasonably designed to alleviate the inconvenience for waitlisted Users of having cabinets in non-contiguous spaces by removing the cost that those Users would otherwise avoid if a cage were available.

The Commission also finds the proposed amendments to the visitor security escort fee consistent with Sections 6(b)(4) and 6(b)(5) of the Act. The Exchange represents that a security escort is not needed when a User visits its own cage because that User would have access only to its own cabinets locked within its own cage,[31] and will not have access to the cabinets of other Users or Exchange equipment, which are locked as well.[32] In addition, the proposed rate of $75/visit for the visitor security escort would be a fee reduction for any visit that lasted more than an hour, and so it would reduce the burden placed on Users that remain subject to the fee. Therefore, the Commission finds the proposed amendments to the visitor security escort fee to be reasonable, equitable, and not unfairly discriminatory.

For the foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the Act.

VII. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[33] that the proposed rule change, as modified by Amendment No.1, (File No. SR–NYSE–2016–13) be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[34]

Brent J. Fields,

Secretary.

[FR Doc. 2016–09724 Filed 4–26–16; 8:45 am]

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[19] *See id.*

[20] *See id.*

[21] As noted above, a User that turns down a cage because it is not the correct size will remain on the waitlist. A User that requests to be removed or that turns down a cage that is the size that it requested will be removed from the waitlist. *See supra* note 17 and accompanying text.

[22] *See* Notice, 81 FR at 13000.

[23] *See id.*

[24] *See id.* The Exchange is also making a technical change to the Price List visitor fee to add clarity. *See id.*

[25] *See id.* The Exchange stated that many of the escorted visits lasted an hour or less. *See id.*

[26] *See id.*

[27] *See id.*

[28] In approving this proposed rule change, as modified by Amendment No. 1, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[29] 15 U.S.C. 78f(b)(4).

[30] 15 U.S.C. 78f(b)(5).

[31] *See supra* notes 26–27 and accompanying text.

[32] *See id.*

[33] 15 U.S.C. 78s(b)(2).

[34] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 32090; File No. 812–14587]

ABS Long/Short Strategies Fund and ABS Investment Management LLC; Notice of Application

April 21, 2016.

AGENCY: Securities and Exchange Commission ("Commission").

ACTION: Notice of an application under section 6(c) of the Investment Company Act of 1940 (the "Act") for an exemption from sections 18(c) and 18(i) of the Act, under sections 6(c) and 23(c)(3) of the Act for an exemption from rule 23c–3 under the Act, and for an order pursuant to section 17(d) of the Act and rule 17d–1 under the Act.

SUMMARY OF APPLICATION: Applicants request an order to permit certain registered closed-end management investment companies to issue multiple classes of shares and to impose asset-based distribution fees and early withdrawal charges ("EWCs").

APPLICANTS: ABS Long/Short Strategies Fund (the "Fund") and ABS Investment Management LLC (the "Adviser").

FILING DATES: The application was filed on December 10, 2015 and amended April 1, 2016.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on May 17, 2016, and should be accompanied by proof of service on the applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090; Applicants: ABS Long/Short Strategies Fund and ABS Investment Management LLC, c/o Edward C. Lawrence, Esq., Bernstein Shur, 100 Middle Street NW., Portland, ME 04104–5029.

FOR FURTHER INFORMATION CONTACT: Jean E. Minarick, Senior Counsel, at (202) 551–8811, or Daniele Marchesani, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. The Fund is a Delaware statutory trust that is registered under the Act as a non-diversified, closed-end management investment company. The Fund's investment objective is to seek capital appreciation over a full market cycle while maintaining a lower level of volatility when compared to the global equity markets.

2. The Adviser is a Delaware limited liability company and is registered as an investment adviser under the Investment Advisers Act of 1940. The Adviser serves as investment adviser to the Fund.

3. The applicants seek an order to permit the Fund to issue multiple classes of shares, each having its own fee and expense structure, and to impose asset-based distribution fees and EWCs.

4. Applicants request that the order also apply to any continuously-offered registered closed-end management investment company that may be organized in the future for which the Adviser or any entity controlling, controlled by, or under common control with the Adviser, or any successor in interest to any such entity,[1] acts as investment adviser and which operates as an interval fund pursuant to rule 23c–3 under the Act or provides periodic liquidity with respect to its shares pursuant to rule 13e–4 under the Securities Exchange Act of 1934 ("Exchange Act") (each, a "Future Fund" and together with the Fund, the "Funds").[2]

5. The Fund is currently making a continuous public offering of its common shares ("Founders' Shares"). Applicants state that additional offerings by any Fund relying on the order may be on a private placement or public offering basis. Shares of the Funds will not be listed on any securities exchange, nor quoted on any quotation medium. The Funds do not expect there to be a secondary trading market for their shares.

6. If the requested relief is granted, the Fund intends to continuously offer at least one additional class of shares ("Institutional Shares") and may also offer additional classes of shares in the future. Because of the different distribution fees, services and any other class expenses that may be attributable to a class of a Fund's shares, the net income attributable to, and the dividends payable on, each class of shares may differ from each other.

7. Applicants state that, from time to time, the Fund may create additional classes of shares, the terms of which may differ from the Founders' Shares and Institutional Shares in the following respects: (i) The amount of fees permitted by different distribution plans or different service fee arrangements; (ii) voting rights with respect to a distribution plan of a class; (iii) different class designations; (iv) the impact of any class expenses directly attributable to a particular class of shares allocated on a class basis as described in the application; (v) any differences in dividends and net asset value resulting from differences in fees under a distribution plan or in class expenses; (vi) any EWC or other sales load structure; and (vii) exchange or conversion privileges of the classes as permitted under the Act.

8. Applicants state that the Fund may provide periodic liquidity with respect to its shares pursuant to rule 13e–4 under the Exchange Act.[3] A Future Fund may adopt a fundamental investment policy to repurchase a specified percentage of its shares in compliance with rule 23c–3 and make quarterly repurchase offers to its shareholders or provide periodic liquidity with respect to its shares pursuant to rule 13e–4 under the Exchange Act. Any repurchase offers made by the Funds will be made to all holders of shares of each such Fund.

9. Applicants represent that any asset-based service and distribution fees for each class of shares will comply with the provisions of NASD Rule 2830(d) ("NASD Sales Charge Rule").[4] Applicants also represent that each Fund will disclose in its prospectus the fees, expenses and other characteristics of each class of shares offered for sale by the prospectus, as is required for open-end multiple class funds under Form N–1A. As is required for open-end funds, each Fund will disclose its expenses in shareholder reports, and describe any arrangements that result in breakpoints in or elimination of sales loads in its prospectus.[5] In addition,

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[1] A successor in interest is limited to an entity that results from a reorganization into another jurisdiction or a change in the type of business organization.

[2] Any Fund relying on this relief in the future will do so in a manner consistent with the terms and conditions of the application. Applicants represent that each entity presently intending to rely on the requested relief is listed as an applicant.

[3] Applicants submit that rule 23c–3 and Regulation M under the Exchange Act permit an interval fund to make repurchase offers to repurchase its shares while engaging in a continuous offering of its shares pursuant to Rule 415 under the Securities Act of 1933.

[4] Any reference to the NASD Sales Charge Rule includes any successor or replacement rule that may be adopted by the Financial Industry Regulatory Authority ("FINRA").

[5] *See* Shareholder Reports and Quarterly Portfolio Disclosure of Registered Management Investment Companies, Investment Company Act Release No. 26372 (Feb. 27, 2004) (adopting release) (requiring open-end investment companies to disclose fund expenses in shareholder reports); and Disclosure of Breakpoint Discounts by Mutual Funds, Investment Company Act Release No. 26464 (June 7, 2004)

Continued

applicants will comply with applicable enhanced fee disclosure requirements for fund of funds, including registered funds of hedge funds.[6]

10. Each of the Funds will comply with any requirements that the Commission or FINRA may adopt regarding disclosure at the point of sale and in transaction confirmations about the costs and conflicts of interest arising out of the distribution of open-end investment company shares, and regarding prospectus disclosure of sales loads and revenue sharing arrangements, as if those requirements applied to the Fund. In addition, each Fund will contractually require that any distributor of the Fund's shares comply with such requirements in connection with the distribution of such Fund's shares.

11. Each Fund will allocate all expenses incurred by it among the various classes of shares based on the net assets of the Fund attributable to each class, except that the net asset value and expenses of each class will reflect distribution fees, service fees, and any other incremental expenses of that class. Expenses of the Fund allocated to a particular class of shares will be borne on a pro rata basis by each outstanding share of that class. Applicants state that each Fund will comply with the provisions of rule 18f–3 under the Act as if it were an open-end investment company.

12. Applicants state that each Fund may impose an EWC on shares submitted for repurchase that have been held less than a specified period and may waive the EWC for certain categories of shareholders or transactions to be established from time to time. Applicants state that each of the Funds will apply the EWC (and any waivers, scheduled variations, or eliminations of the EWC) uniformly to all shareholders in a given class and consistently with the requirements of rule 22d–1 under the Act as if the Funds were open-end investment companies.

13. Each Fund operating as an interval fund pursuant to rule 23c–3 under the Act may offer its shareholders an exchange feature under which the shareholders of the Fund may, in connection with the Fund's periodic repurchase offers, exchange their shares of the Fund for shares of the same class of (i) registered open-end investment companies or (ii) other registered closed-end investment companies that comply with rule 23c–3 under the Act and continuously offer their shares at net asset value, that are in the Fund's group of investment companies (collectively, "Other Funds"). Shares of a Fund operating pursuant to rule 23c–3 that are exchanged for shares of Other Funds will be included as part of the amount of the repurchase offer amount for such Fund as specified in rule 23c–3 under the Act. Any exchange option will comply with rule 11a–3 under the Act, as if the Fund were an open-end investment company subject to rule 11a–3. In complying with rule 11a–3, each Fund will treat an EWC as if it were a contingent deferred sales load ("CDSL").

Applicants' Legal Analysis

Multiple Classes of Shares

1. Section 18(c) of the Act provides, in relevant part, that a closed-end investment company may not issue or sell any senior security if, immediately thereafter, the company has outstanding more than one class of senior security. Applicants state that the creation of multiple classes of shares of the Funds may be prohibited by section 18(c), as a class may have priority over another class as to payment of dividends because shareholders of different classes would pay different fees and expenses.

2. Section 18(i) of the Act provides that each share of stock issued by a registered management investment company will be a voting stock and have equal voting rights with every other outstanding voting stock. Applicants state that multiple classes of shares of the Funds may violate section 18(i) of the Act because each class would be entitled to exclusive voting rights with respect to matters solely related to that class.

3. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction or any class or classes of persons, securities or transactions from any provision of the Act, or from any rule or regulation under the Act, if and to the extent such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants request an exemption under section 6(c) from sections 18(c) and 18(i) to permit the Funds to issue multiple classes of shares.

4. Applicants submit that the proposed allocation of expenses relating to distribution and voting rights among multiple classes is equitable and will not discriminate against any group or class of shareholders. Applicants submit that the proposed arrangements would permit a Fund to facilitate the distribution of its shares and provide investors with a broader choice of shareholder services. Applicants assert that the proposed closed-end investment company multiple class structure does not raise the concerns underlying section 18 of the Act to any greater degree than open-end investment companies' multiple class structures that are permitted by rule 18f–3 under the Act. Applicants state that each Fund will comply with the provisions of rule 18f–3 as if it were an open-end investment company.

Early Withdrawal Charges

1. Section 23(c) of the Act provides, in relevant part, that no registered closed-end investment company shall purchase securities of which it is the issuer, except: (a) On a securities exchange or other open market; (b) pursuant to tenders, after reasonable opportunity to submit tenders given to all holders of securities of the class to be purchased; or (c) under other circumstances as the Commission may permit by rules and regulations or orders for the protection of investors.

2. Rule 23c–3 under the Act permits a registered closed-end investment company (an "interval fund") to make repurchase offers of between five and twenty-five percent of its outstanding shares at net asset value at periodic intervals pursuant to a fundamental policy of the interval fund. Rule 23c–3(b)(1) under the Act permits an interval fund to deduct from repurchase proceeds only a repurchase fee, not to exceed two percent of the proceeds, that is paid to the interval fund and is reasonably intended to compensate the fund for expenses directly related to the repurchase.

3. Section 23(c)(3) provides that the Commission may issue an order that would permit a closed-end investment company to repurchase its shares in circumstances in which the repurchase is made in a manner or on a basis that does not unfairly discriminate against any holders of the class or classes of securities to be purchased.

4. Applicants request relief under section 6(c), discussed above, and section 23(c)(3) from rule 23c–3 to the extent necessary for the Funds to impose EWCs on shares of the Funds submitted for repurchase that have been held for less than a specified period.

5. Applicants state that the EWCs they intend to impose are functionally similar to CDSLs imposed by open-end investment companies under rule 6c–10

(adopting release) (requiring open-end investment companies to provide prospectus disclosure of certain sales load information).

[6] Fund of Funds Investments, Investment Company Act Rel. Nos. 26198 (Oct. 1, 2003) (proposing release) and 27399 (Jun. 20, 2006) (adopting release). *See* also Rules 12d1–1, *et seq.* of the Act.

under the Act. Rule 6c–10 permits open-end investment companies to impose CDSLs, subject to certain conditions. Applicants note that rule 6c–10 is grounded in policy considerations supporting the employment of CDSLs where there are adequate safeguards for the investor and state that the same policy considerations support imposition of EWCs in the interval fund context. In addition, applicants state that EWCs may be necessary for the distributor to recover distribution costs. Applicants represent that any EWC imposed by the Funds will comply with rule 6c–10 under the Act as if the rule were applicable to closed-end investment companies. The Funds will disclose EWCs in accordance with the requirements of Form N–1A concerning CDSLs.

Asset-Based Distribution Fees

1. Section 17(d) of the Act and rule 17d–1 under the Act prohibit an affiliated person of a registered investment company, or an affiliated person of such person, acting as principal, from participating in or effecting any transaction in connection with any joint enterprise or joint arrangement in which the investment company participates unless the Commission issues an order permitting the transaction. In reviewing applications submitted under section 17(d) and rule 17d–1, the Commission considers whether the participation of the investment company in a joint enterprise or joint arrangement is consistent with the provisions, policies and purposes of the Act, and the extent to which the participation is on a basis different from or less advantageous than that of other participants.

2. Rule 17d–3 under the Act provides an exemption from section 17(d) and rule 17d–1 to permit open-end investment companies to enter into distribution arrangements pursuant to rule 12b–1 under the Act. Applicants request an order under section 17(d) and rule 17d–1 under the Act to the extent necessary to permit the Funds to impose asset-based distribution fees. Applicants have agreed to comply with rules 12b–1 and 17d–3 as if those rules applied to closed-end investment companies, which they believe will resolve any concerns that might arise in connection with a Fund financing the distribution of its shares through asset-based distribution fees.

3. For the reasons stated above, applicants submit that the exemptions requested under section 6(c) are necessary and appropriate in the public interest and are consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants further submit that the relief requested pursuant to section 23(c)(3) will be consistent with the protection of investors and will insure that applicants do not unfairly discriminate against any holders of the class of securities to be purchased. Finally, applicants state that the Funds' imposition of asset-based distribution fees is consistent with the provisions, policies and purposes of the Act and does not involve participation on a basis different from or less advantageous than that of other participants.

Applicants' Condition

Applicants agree that any order granting the requested relief will be subject to the following condition:

Each Fund relying on the order will comply with the provisions of rules 6c–10, 12b–1, 17d–3, 18f–3, 22d–1, and, where applicable, 11a–3 under the Act, as amended from time to time, as if those rules applied to closed-end management investment companies, and will comply with the NASD Sales Charge Rule, as amended from time to time, as if that rule applied to all closed-end management investment companies.

For the Commission, by the Division of Investment Management, under delegated authority.

Brent J. Fields,

Secretary.

[FR Doc. 2016–09715 Filed 4–26–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77674; File No. SR–NYSE–2016–22)

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing of Proposed Rule Change Adopting Initial and Continued Listing Standards for the Listing of Equity Investment Tracking Stocks and Adopting Listing Fees Specific to Equity Investment Tracking Stocks

April 21, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 ("Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on April 7, 2016, New York Stock Exchange LLC ("NYSE" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to adopt initial and continued listing standards for the listing of Equity Investment Tracking Stocks. The Exchange also proposes to adopt listing fees specific to Equity Investment Tracking Stocks. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to adopt initial and continued listing standards for the listing of Equity Investment Tracking Stocks. The Exchange also proposes to adopt listing fees specific to Equity Investment Tracking Stocks.

For purposes of proposed new Section 102.07 of the Manual, an Equity Investment Tracking Stock refers to a class of common stock that is the listed company's sole class of common equity securities listed on the Exchange and that is designed solely to track the performance of an investment by the issuer in the common stock of another company listed on the Exchange.

In order to qualify for initial listing under proposed Section 102.07, an Equity Investment Tracking Stock will be required to meet the distribution and public float requirements currently applicable for initial public offerings set forth in Sections 102.01A and 102.01B of the Manual, respectively, and the quantitative requirements set forth in Section 102.01C. As such, as required under Section 102.01A, an Equity Investment Tracking Stock, at the time of initial listing, will be required to have at least 400 holders of 100 shares or more and 1,100,000 public held shares available for trading. Further, as required under Section 102.01B, an Equity Investment Tracking Stock must have an aggregated market value of publicly-held shares of $40,000,000 and a per share price of $4 at the time of initial listing. Under Section 102.01C, the issuer of an Equity Investment Tracking Stock will be required to meet either the Earnings Test or the Global Market Capitalization Test. Under the Earnings test, an issuer must have pre-tax earnings totaling (x) at least $10,000,000 in the aggregate for the last three fiscal years together with a minimum of $2,000,000 in each of the two most recent fiscal years, and positive amounts in all three years or (y) at least $12,000,000 in the aggregate for the last three fiscal years together with a minimum of $5,000,000 in the most recent fiscal year and $2,000,000 in the next most recent fiscal year.[4] Under the Global Market Capitalization Test, the issuer must have $200 million in global market capitalization at the time of initial listing.

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[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

The Exchange will not list an Equity Investment Tracking Stock if, at the time of the proposed listing, the issuer of the equity tracked by the Equity Investment Tracking Stock has been deemed below compliance with listing standards by the Exchange.

The Exchange proposes to subject the issuer of an Equity Investment Tracking Stock to the same continued listing standards under Sections 802.01A and 802.01B as are applicable to other companies listing common stocks on the Exchange. As such, these companies will be considered to be below compliance with Section 802.01A if (i) their number of total stockholders is less than 400 OR (ii) their number of total stockholders is less than 1,200 and their average monthly trading volume is less than 100,000 shares (for the most recent 12 months) OR (iii) their number of publicly-held shares is less than 600,000. Such companies will be deemed to be below compliance with Section 802.01B if their average global market capitalization over a consecutive 30 trading-day period is less than $50,000,000 and, at the same time stockholders' equity is less than $50,000,000 and (will be subject to immediate delisting if they are determined to have average global market capitalization over a consecutive 30 trading-day period of less than $15,000,000. In addition, the Exchange will promptly initiate suspension and delisting proceedings with respect to an Equity Investment Tracking Stock if the underlying equity security whose value is tracked by the Equity Investment Tracking Stock ceases to be listed on one of (i) the Exchange, (ii) the Nasdaq Stock Market, (iii) NYSE MKT or (iv) one of the markets listed in SEC Rule 146(b)[5] or is converted into or exchanged for another security that is not listed on one of the aforementioned markets.

The Exchange proposes to amend Sections 902.02 and 902.03 of the Manual to provide that, where an Equity Investment Tracking Stock is listed on the Exchange, listing and annual fees for such security will be subject to a single fee cap at the time of original listing and on an annual basis. The Exchange further proposes to amend Section 907.00 of the Manual to limit the products and services provided to the issuer of an Equity Investment Tracking Stock. The proposed fees would apply to the initial and continued listing on the Exchange of an Equity Investment Tracking Stock and to the products and services provided to issuers of such security for as long as the Equity Investment Tracking Stock is the only class of security that is listed on the Exchange.

Pursuant to Section 902.02 and 902.03 of the Manual, listed companies are charged an annual security fee for each class or series of security listed on the Exchange. The annual fee is calculated based on the number of shares issued and outstanding and is currently set at a rate of $0.001025 for the primary listed class of equity, subject to an annual minimum of $52,500. In its first year of listing, a company's annual fee is prorated from the date of initial listing through the year end. Listed companies also pay other fees to the Exchange, including fees associated with initial and supplemental listing applications. In any given calendar year, however, Section 902.02 of the Manual specifies that the total fees that the Exchange may bill a listed company are capped at $500,000 (the "Total Maximum Fee"). For an Equity Investment Tracking Stock, the Exchange proposes to adopt a Total Maximum Fee of $200,000.

Section 902.03 of the Manual currently provides, in part, for listing fees the first time an issuer lists a class of common shares, charged on a per share basis based on tiers set forth in the rule. The first time that an issuer lists a class of common shares, the issuer is also subject to a one-time special charge of $50,000. Once listed, if an issuer lists additional shares of a class of previously listed securities, the issuer is subject to listing fees for such additional shares. The minimum and maximum listing fees applicable the first time an issuer lists a class of common shares are $125,000 and $250,000, respectively, which amounts include the special charge of $50,000. In lieu of the foregoing, the Exchange proposes to establish for Equity Investment Tracking Stocks a fixed initial listing fee (inclusive of the one-time charge) of $100,000. Subject to the Total Maximum Fee of $200,000 per year described above, the Exchange proposes to charge the same per share annual fee for Equity Investment Tracking Stocks as for the primary class of equity of a listed operating company (*i.e.*, currently $0.001025 per share).

Finally, Section 907.00 of the Manual sets forth certain complimentary products and services that are offered to certain currently and newly listed issuers. These products and services are developed or delivered by NYSE or by a third party for use by NYSE-listed companies. Some of these products are commercially available from such third-party vendors. All listed issuers receive some complimentary products and services through the NYSE Market Access Center. The Exchange proposes to exclude issuers of an Equity Investment Tracking Stock from receiving the products and services provided for under Section 907.00, with the exception that such issuers will receive the complimentary products and services and access to discounted third-party products and services through the NYSE Market Access Center available to all listed issuers.

The Exchange proposes to limit the fees that would be payable for the listing on an Equity Investment Tracking Stock as an incentive for the issuer to list such security on the Exchange. As described below, the Exchange proposes to make the aforementioned fee changes to better reflect the Exchange's costs related to listing Equity Investment Tracking Stocks and the corresponding value of such listing to issuers.

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[4] A company that (i) qualifies as an emerging growth company as defined in Section 2(a)(19) of the Securities Act and Section 3(a)(80) of the Exchange Act and (ii) avails itself of the provisions of the Securities Act and the Exchange Act permitting emerging growth companies to report only two years of audited financial statements, can qualify under the Earnings Test by meeting the following requirements: Pre-tax earnings totaling at least $10,000,000 in the aggregate for the last two fiscal years together with a minimum of $2,000,000 in both years.

[5] 17 CFR 230.146(b).

The Exchange proposes to make three other minor changes in this filing: (i) To remove from Section 902.03 references to the annual fee schedule applicable to years prior to 2016; (ii) to update the web link included in Section 907.00 and (iii) to delete the word "four" from Section 802.01B, as there are no longer four continued listing standards referred to in that rule.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[6] in general, and furthers the objectives of Sections 6(b)(4)[7] and 6(b)(5)[8] of the Act, in particular.

The Exchange believes that the proposed initial and continued listing standards for Equity Investment Tracking Stocks further the objectives of Section 6(b)(5) of the Act,[9] in particular in that they are designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. In particular, the proposed listing standards are designed to protect investors and the public interest by ensuring that Equity Investment Tracking Stocks listed on the Exchange meet stringent quantitative and qualitative listing standards to qualify for initial and continued listing.

The proposed fee provisions further the objectives of Sections 6(b)(4) in that they are designed to provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities. The Exchange believes that the proposed fee provisions are consistent with Section 6(b)(5) of the Act in that they do not unfairly discriminate among listed companies because there is a reasonable justification for charging the issuer of an Equity Investment Tracking Stock different fees from those charged to other issuers as there are cost and regulatory efficiencies for the Exchange when the issuer of an Equity Investment Tracking Stock and the issuer of the underlying equity security are both listed on the Exchange. Under the Exchange's proposal, the issuer of an Equity Investment Tracking Stock would pay a fixed initial listing fee of $100,000, which is less than the minimum fee charged in connection with the listing of the primary class of equity of an operating company. In addition, Equity Investment Tracking Stocks would be billed annual fees at the same rate per share as the primary class of equity of an operating company, but subject to a lower annual fee cap that may cause an issuer of an Equity Investment Tracking Stock to be subject to a lower effective fee rate per share than if it were a regular operating company. Given the unique nature of an Equity Investment Tracking Stock, including especially the fact that its trading price will likely be primarily derivative of the trading price of the security of another company, most of the services provided by the Exchange under Section 907.00 would be of limited value and appeal to issuers of Equity Investment Tracking Stocks and the Exchange believes it is appropriate to exclude the issuers of Equity Investment Tracking Stocks from its services program. The Exchange believes that the fact that it will not provide these costly services makes it appropriate to charge lower fees. In addition, the Exchange believes there will be regulatory efficiencies when the same regulatory staff is responsible for oversight of an Equity Investment Tracking Stock and the underlying equity security. This would include, for example, the fact that news that is material to the issuer of the underlying security would also be material to an investment in the Equity Investment Tracking Stock.

The Exchange does not expect many issuers will seek to list an Equity Investment Tracking Stock. Accordingly, the Exchange does not anticipate that it will experience any meaningful diminution in revenue as a result of the proposed lower fees and therefore does not believe that the proposed fees would in any way negatively affect its ability to continue to adequately fund its regulatory program or the services the Exchange provides to issuers

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is designed to provide listing standards for Equity Investment Tracking Stocks that are appropriately protective of investors and is not designed to limit the ability of the issuers of those securities to list them on any other national securities exchange. The proposed rule change is designed to ensure that the fees charged by the Exchange accurately reflect the services provided and benefits realized by listed companies. The market for listing services is extremely competitive. Each listing exchange has a different fee schedule that applies to issuers seeking to list securities on its exchange. Issuers have the option to list their securities on these alternative venues based on the fees charged and the value provided by each listing. Because issuers have a choice to list their securities on a different national securities exchange, the Exchange does not believe that the proposed listing standards and fee changes impose a burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or *up to 90 days* (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSE–2016–22 on the subject line.

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[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(4).

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78f(b)(5).

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2016–22. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSE–2016–22, and should be submitted on or before May 18, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Brent J. Fields,

Secretary.

[FR Doc. 2016–09717 Filed 4–26–16; 8:45 am]

BILLING CODE 8011–01–P

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[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–77675; File No. SR–FICC–2016–001]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing of Proposed Rule Change Relating to the GCF Repo® Service

April 21, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 19, 2016, the Fixed Income Clearing Corporation ("FICC" or the "Corporation") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared primarily by FICC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of amendments to the Government Securities Division ("GSD") Rulebook[3] ("GSD Rules") in order to: (1) Permanently adopt the pilot program (the "2015 Pilot Program")[4] that is currently in effect for the GCF Repo®[5] service and that is scheduled to expire on June 22, 2016; (2) add clarifying rule changes regarding a process that is currently in effect with respect to the GCF Repo service and that FICC refers to as the "net-of-net" settlement process; and (3) make technical changes to the GSD Rules. The proposed rule changes consist of changes to GSD Rule 1, GSD Rule 20 and the *Schedule of GCF Timeframes.*

Capitalized terms used herein and not otherwise defined shall have the meaning assigned to those terms in the GSD Rules.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

i. Background: Description of the GCF Repo Service and History

(1) Development of the GCF Repo Service

The GCF Repo service was developed as part of a collaborative effort among the Government Securities Clearing Corporation ("GSCC") (FICC's predecessor), its two clearing banks (The Bank of New York Mellon ("BNY") and JPMorgan Chase Bank, National Association ("Chase")) and industry representatives. GSCC introduced the GCF Repo service on an *intra*-clearing bank basis in 1998.[6] Under the intrabank service, Dealers[7] could only engage in GCF Repo Transactions[8] with other Dealers that cleared at the *same* clearing bank.

Currently, the GCF Repo service allows Netting Members[9] that participate in the service to trade general collateral repos[10] throughout the day without requiring intra-day, trade-for-trade settlement on a delivery-versus-payment ("DVP") basis. The service allows Dealers to trade such general collateral repos, based on rate and term, throughout the day with Inter-Dealer Broker Netting Members[11] on a blind basis. Standardized Generic CUSIP Numbers[12] have been established exclusively for GCF Repo processing and are used to specify the acceptable type of underlying Fedwire book-entry eligible collateral, which includes Treasuries, Agencies and certain mortgage-backed securities.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The GSD Rulebook is available at DTCC's Web site, *www.dtcc.com/legal/rules-and-procedures.aspx.*

[4] Securities Exchange Act Release No. 34–75258 (June 22, 2015), 80 FR 36879 (June 26, 2015) (SR–FICC–2015–002).

[5] GCF Repo is a registered trademark of FICC/DTCC.

[6] Securities Exchange Act Release No. 34–40623 (October 30, 1998) 63 FR 59831 (November 5, 1998) (SR–GSCC–98–02).

[7] Pursuant to the GSD Rules, the term "Dealer" means a member that is a registered Government Securities Dealer. GSD Rule 1, Definitions.

[8] Pursuant to the GSD Rules, the term "GCF Repo Transaction" means a Repo Transaction involving Generic CUSIP Numbers the data on which are submitted to the Corporation on a Locked-In-Trade basis pursuant to the provisions of Rule 6C, for netting and settlement by the Corporation pursuant to the provisions of Rule 20. GSD Rule 1, Definitions.

[9] Pursuant to the GSD Rules, the term "Netting Member" means a Member that is a Member of the Comparison System and the Netting System. GSD Rule 1, Definitions.

[10] A general collateral repo is a repo in which the underlying securities collateral is nonspecific, general collateral whose identification is at the option of the seller. This is in contrast to a specific collateral repo.

[11] Pursuant to the GSD Rules, the term "Inter-Dealer Broker Netting Member" shall have the meaning set forth in Section 2 of Rule 2A. GSD Rule 1, Definitions.

[12] Pursuant to the GSD Rules, the term "Generic CUSIP Number" means a Committee on Uniform Securities Identification Procedures identifying number established for a category of securities, as opposed to a specific security. The Corporation shall use separate Generic CUSIP Numbers for General Collateral Repo Transactions and GCF Repo Transactions. GSD Rule 1, Definitions.

(2) Creation of the Interbank Version of the GCF Repo Service

In 1999, GSCC expanded the GCF Repo service to permit Dealers to engage in GCF Repo trading on an *inter*-clearing bank basis, meaning that Dealers using *different* clearing banks could enter into GCF Repo Transactions (on a blind brokered basis).[13] Because Dealers that participate in the GCF Repo service do not all clear at the same clearing bank, introducing the service as an interbank service necessitated the establishment of a mechanism to permit after-hours movements of securities between the two clearing banks to deal with the fact that GSCC would likely have unbalanced net GCF securities and cash positions within each clearing bank (meaning that, it is likely that at the end of GCF Repo processing each business day, the Dealers in one clearing bank will be net funds borrowers, while the Dealers at the other clearing bank will be net funds lenders). To address this issue, GSCC and its clearing banks established, and the Commission approved, a legal mechanism by which securities would "move" across the clearing banks without the use of the securities Fedwire.[14] Therefore, at the end of the day, after the GCF Net Settlement Position[15] results are produced, securities are pledged via a tri-party-like mechanism and the interbank cash component is moved via Fedwire. In the morning, the pledges are unwound (meaning that funds are returned to the net funds lenders and securities are returned to the net funds borrowers).

The following simplified example illustrates the manner in which the GCF Repo services works on an *interbank* basis:

Assume that Dealer B clears at BNY and Dealer C clears at Chase. Further assume that: (i) Outside of FICC, Dealer B engages in a tri-party repo transaction with Party X to obtain funds and seeks to invest such funds via a GCF Repo Transaction, (ii) outside of FICC, Dealer C engages in a DVP repo with Party Y to buy securities and seeks to finance these securities via a GCF Repo Transaction, and (iii) Dealer B and Dealer C enter into a GCF Repo Transaction (on a blind basis via a GCF Repo broker) and submit the trade details to FICC.

At the end of "Day 1", GCF Repo collateral must be allocated, *i.e.*, Dealer B must receive the securities. However, the securities that Dealer B is to receive are at Chase and the securities Fedwire is closed. The after-hours movement mechanism permits the securities to be "sent" to Dealer B as follows: FICC will instruct Chase to allocate to a special FICC clearance account at Chase securities in an amount equal to the net short securities position.

FICC has established on its own books and records two "securities accounts" as defined in Article 8 of the New York Uniform Commercial Code, one in the name of Chase ("FICC Account for Chase") and one in the name of BNY ("FICC Account for BNY"). The FICC Account for Chase is comprised of the securities in FICC's special clearance account maintained by BNY ("FICC Special Clearance Account at BNY for Chase"), and the FICC Account for BNY is comprised of the securities in FICC's special clearance account maintained by Chase ("FICC Special Clearance Account at Chase for BNY").[16] The establishment of these securities accounts by FICC in the name of the clearing banks enables the bank that is in the net long securities position to "receive" securities by pledge after the close of the securities Fedwire. Once the clearing bank has "received" the securities by pledge, it can credit them by book-entry to a FICC GCF Repo account at that clearing bank and then to the Dealers that clear at that bank that are net long the securities in connection with GCF Repo trades.

In the example, Chase, as agent for FICC, will transmit to BNY a description of the securities in the FICC Special Clearance Account at Chase for BNY. Based on this description, BNY will transfer funds equal to the funds borrowed position to the FICC GCF Repo account at Chase. Upon receipt of the funds by Chase, Chase will release any liens it may have on the FICC Special Clearance Account at Chase for BNY, and FICC will release any liens it may have on FICC Account for BNY (both of these accounts being comprised of the same securities). BNY will credit the securities in the FICC Account for BNY to FICC's GCF Repo account at BNY, and BNY will further credit these securities to Dealer B, who, as noted, is in a net long securities position. In the morning of "Day 2," all securities and funds movements occurring on Day 1, are reversed ("unwind").

(3) Issues With Morning Unwind Process

In 2003, FICC shifted the GCF Repo service back to intrabank status only.[17] By that time, the service had grown significantly in participation and volume. However, with the increase in use of the interbank service, certain payments systems risk issues arose from the inter-bank funds settlements related to the service, namely, the large interbank funds movement in the morning. FICC shifted the service back to intrabank status to enable management to study the issues presented and identify a satisfactory solution for bringing the service back to interbank status.

(4) The NFE Filing and Restoration of Service to Interbank Status

In 2007, FICC submitted a rule filing to address the issues raised by the interbank morning funds movement and return the GCF Repo service to interbank status (the "2007 NFE Filing").[18] The 2007 NFE Filing addressed these issues by using a hold against a Dealer's "net free equity" ("NFE") at the clearing bank to collateralize its GCF Repo cash obligation to FICC on an intraday basis.[19]

ii. Annual Pilot Program, and Reasons for Adopting the Pilot Program Permanently

In July 2011, FICC submitted a rule filing to the Commission (SR–FICC–2011–05)[20] proposing to make certain changes to its GCF Repo service in order to comply with the recommendations that had been made by the Tri-party Repo Infrastructure Reform Task Force ("TPR"),[21] an industry group formed and sponsored by the Federal Reserve Bank of New York to advance tri-party repo reform recommendations.[22] Because the GCF Repo service operates as a tri-party mechanism, FICC was requested to incorporate changes to the GCF Repo service to align the service with the other TPR recommended changes for the overall tri-party market. In SR–FICC–2011–05, FICC proposed the following rule changes with respect to the GCF Repo service to address the TPR's Recommendations:

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[13] Securities Exchange Act Release No. 34–41303 (April 16, 1999) 64 FR 20346 (April 26, 1999) (SR–GSCC–99–01).

[14] *See id.* for a detailed description of the clearing bank and FICC accounts needed to effect the after hour movement of securities. It should be noted that movements of cash do not present the same issue because the cash Fedwire is open later than the securities Fedwire.

[15] Pursuant to the GSD Rules, the term "GCF Net Settlement Position" means, on a particular Business Day as regards a Netting Member's GCF Repo Transaction activity in a particular Generic CUSIP Number, either a GCF Net Funds Lender Position or a GCF Net Funds Borrower Position, as the context requires. *See* GSD Rule 1, Definitions.

[16] FICC has appointed Chase as its agent to maintain FICC's books and records with respect to the BNY securities account, and FICC has appointed BNY as its agent to maintain FICC's books and records with respect to the Chase securities account.

[17] Securities Exchange Act Release No. 34–48006 (June 10, 2003), 66 FR 35745 (June 16, 2003) (SR–FICC–2003–04).

[18] Securities Exchange Act Release No. 34–57652 (April 11, 2008), 73 FR 20999 (April 17, 2008) (SR–FICC–2007–08).

[19] NFE is a methodology that clearing banks use to determine whether an account holder (such as a dealer) has sufficient collateral to enter a specific transaction. NFE allows the clearing bank to place a limit on its customer's activity by calculating a value on the customer's balances at the bank. Bank customers have the ability to monitor their NFE balance throughout the day.

[20] Securities Exchange Act Release No. 34–65213 (August 29, 2011), 76 FR 54824 (September 2, 2011) (SR–FICC–2011–05).

(1) (a) To move the Day 2 unwind from 7:30 a.m. to 3:30 p.m., (b) to move the NFE process from morning to a time established by the Corporation as announced by notice to all members, (c) to move the cut-off time of GCF Repo submissions from 3:35 p.m. to 3:00 p.m., and (d) to move the cut-off time for dealer affirmation or disaffirmation from 3:45 p.m. to 3:00 p.m.; and

(2) To establish rules for intraday GCF Repo collateral substitutions.

The rule changes described in SR–FICC–2011–05 were proposed to be run as a pilot program for one year starting from the date on which the filing was approved by the Commission (the "2011 Pilot Program").[23] Throughout 2011 and the earlier half of 2012, FICC implemented the changes referred to in paragraphs *(1)*(c) and *(1)*(d) above. On June 8, 2012, FICC submitted a rule filing to continue the 2011 Pilot Program, with certain modifications (the "2012 Pilot Program").[24] Specifically, the 2012 Pilot Program adopted the following additional changes: (1) The cut-off time for GCF Repo trade submissions was moved from 3:35 p.m. to 3:00 p.m.; (2) the 3:45 p.m. cut-off time for Dealer affirmation or disaffirmation was moved from 3:45 p.m. to 3:00 p.m.; (3) Rule 20 Section 3 was amended to delete the reference to the "morning" timeframe on Day 2 with respect to the NFE process and to add language referencing "at the time established by the Corporation"; (4) Rule 20 Section 3 was amended to provide that all requests for GCF Repo securities collateral substitutions must be submitted by the GCF Repo securities collateral provider by the applicable deadline on Day 2 (the "substitution deadline"); (5) Rule 20 Section 7 was amended to change references to the term "Security" to "security" to conform to the use of "security" throughout the rule; and (6) a defined term for "GCF Collateral Excess Account" was introduced into the GSD Rules. For the next 3 years after that, FICC submitted and the Commission approved rule filings to extend the pilot while the industry was implementing Tri-Party Reform and adapting to the changes brought about by Tri-Party Reform.[25]

FICC is seeking the Commission's approval to permanently adopt the rule changes associated with the 2015 Pilot Program, which expires on June 22, 2016. In addition, FICC is also seeking to add a clarification to the GSD Rules to reflect the net-of-net settlement process in the GCF Repo service, as further explained below. The net-of-net settlement clarification is also a result of Tri-Party Reform and reflects current practice at the GSD. FICC would like to permanently adopt these changes because there is no longer a need to keep extending the pilot. The rule changes associated with the pilot have been in place since 2011 with certain additional modifications that were made in connection with the 2012 Pilot Program, and Netting Members are accustomed to them; this is also the case with the net-of-net settlement changes, which came into effect when the clearing banks implemented this process in 2014 and 2015. This change required no operational changes on the part of FICC; however, FICC is proposing to make changes to the GSD Rules in an effort to ensure that the Rules reflect the current net-of-net settlement process. Any future changes that arise as a result of Tri-Party Reform will constitute stand-alone rule changes and are not expected to affect the rule changes covered in this present filing.

In addition to the above, FICC is also proposing to amend the GSD Rules to include technical clean-up changes to the GSD Rules.

iii. The Manner in Which the Proposed Rule Change Will Affect GSD Netting Members

FICC does not believe that the permanent adoption of the rule changes associated with the 2015 Pilot Program will affect Netting Members because the proposed rule changes have been in place since the approval of the 2011 and 2012 pilot-related filings.[26] In addition, FICC does not believe that the inclusion of the rule changes associated with the net-of-net settlement will affect Netting Members because these changes are also in effect and reflect current practice.

The proposed technical changes will not affect Netting Members because they do not change the existing meaning of the GSD Rules.

These rule changes are as follows:

(1) Proposed Change Regarding the Morning Unwind and Related Rule Changes

At the beginning of the Tri-Party Reform effort, the TPR recommended that the daily unwind[27] for all tri-party transactions be moved from the morning to 3:30 p.m. The TPR made this recommendation in order to achieve the benefit of reducing the banks' intraday exposure to the Dealers. Because the GCF Repo service is essentially a tri-party mechanism, the TPR requested that FICC accommodate this time change. For the GSD Rules, this necessitated a change to the GSD's *Schedule of GCF Timeframes.* Specifically, the 7:30 a.m. time in the *Schedule of GCF Timeframes* was deleted and the language therein was moved to a new time of 3:30 p.m. Because the net-of-net settlement process has now replaced the unwind, as further described below, FICC is further amending the language for the 3:30 p.m. time slot to reflect the net-of-net settlement process.

At the same time as the change to the time of the unwind needed to be made, GSD was also required to make an additional change to its processes in conjunction with the move of the unwind to 3:30 p.m. As noted above, the NFE process works in conjunction with the unwind. The process utilizes a hold against a Netting Member's NFE at the clearing bank to collateralize the Netting Member's GCF Repo cash obligation to FICC on an intraday basis. As part of Tri-Party Reform, because the unwind moved from the morning to 3:30 p.m. and because the NFE process was tied to the moment of the unwind, the NFE process also was required to move to coincide with the new time. As part of the pilot, the necessary rule change was made to the paragraph in Section 3 of GSD Rule 20 that addresses the NFE process to delete the reference to the "morning" timeframe and to replace it with general language referencing "at the time established by the Corporation." Because the net-of-net settlement process has now replaced the unwind, as further described below, FICC is further amending the language in the NFE paragraph to reflect the net-of-net settlement process by deleting the reference to "Day 2" and replacing it with "a particular Business Day."

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[21] Information about the Federal Reserve's Tri-party Repo Infrastructure Reform is available via *http://www.newyorkfed.org/banking/tpr_infr_reform.html.*

[22] The main purpose of the TPR was to develop recommendations to address the risk presented by tri-party repo transactions due to the morning reversal or "unwind" process and to move to a process by which transactions are collateralized all day. The TPR's efforts shall hereinafter be referred to as "Tri-party Reform."

[23] Securities Exchange Act Release No. 34–65213 (August 29, 2011), 76 FR 54824 (September 2, 2011) (SR–FICC–2011–05).

[24] Securities Exchange Release No. 34–67621 (August 8, 2012), 77 FR 48572 (August 14, 2012) (SR–FICC–2012–05).

[25] Securities Exchange Act Release No. 34–70068 (July 30, 2013), 78 FR 47453 (August 5, 2013) (SR–FICC–2013–06); Securities Exchange Act Release No. 34–72457 (June 24, 2014), 79 FR 36856 (June 30, 2014) (SR–FICC–2014–02); and Securities Exchange Act Release No. 34–75258 (June 22, 2015), 80 FR 36879 (SR–FICC–2015–002).

[26] *See* footnotes 23 and 24 above.

[27] *See* footnote 22 above.

The change to the time of the unwind also necessitated a change to the cut-off time for GCF Repo trade submissions in the *Schedule of GCF Timeframes* to an earlier time of 3:00 p.m. in order to allow FICC time to submit files to the clearing banks which, in turn, provide files to Netting Members by 3:30 p.m. This permits Netting Members to have a complete picture of their positions as the unwind (now the net-of-net) occurs at 3:30 p.m. In addition, the 3:45 p.m. cut-off for Dealer affirmation or disaffirmation in the *Schedule of GCF Timeframes* was moved to 3:00 p.m. so that the new 3:00 p.m. cut-off for submissions also became the cut-off for Dealer affirmations and disaffirmations.

(2) Proposed Change Regarding Intraday GCF Repo Securities Collateral Substitutions

As a result of moving the time change of the unwind (which is now the net-of-net settlement process) to 3:30 p.m., the provider of the GCF Repo securities collateral needs a substitution mechanism for the return of its posted collateral in order to make securities deliveries for utilization of such securities in its business activities. The 2015 Pilot Program rule filing (and the previous pilot filings) added a paragraph to Section 3 of Rule 20 to accommodate intraday substitution of collateral. In this filing FICC is further amending this paragraph in Section 3 of Rule 20 to delete "During Day 2" and replace it with "On any Business Day" to accommodate the net-of-net settlement process.

If the GCF Repo Transaction is between Netting Member counterparties effecting the transaction through the same clearing bank (*i.e.*, intrabank), such clearing bank will process each substitution request of the provider of GCF Repo securities collateral submitted prior to the substitution deadline. Netting Members are able to substitute GCF Repo collateral during the day until such time as their new requirement for that day is fully satisfied and delivered to GSD. For a GCF Repo Transaction that was processed on an interbank basis, FICC initiates a debit of the securities in the account of the lender through the FICC GCF Repo account at the clearing bank of the lender and the FICC GCF Repo account at the clearing bank of the borrower. This movement is done so that a borrower who elects to substitute collateral will have access to the collateral for which it is substituting. This is reflected in the *Schedule of GCF Repo Timeframes* as the timeframe of 7:30 a.m. through 2:30 p.m. Once the debit has settled, borrowers can submit substitution requests until the substitution deadline.

(3) Proposed Changes Regarding the Net-of-Net Settlement Process

As stated above, as part of the Tri-party Reform effort, GCF Repo Transactions are no longer unwound in the sense of having a reversal of the activity of the previous day. Instead, new obligations and entitlements are netted with the previous day's obligations and entitlements, thereby requiring settlement of only the differential between the previous day's activity and the new activity. To illustrate, consider the scenario in which a Netting Member has on a Business Day a $100 million delivery obligation to FICC, and on the following Business Day, the same Netting Member has a $110 million delivery obligation to FICC in the same Generic CUSIP Number. Prior to the net-of-net implementation, to unwind the first Business Day's transaction, FICC would have returned the $100 million on the second Business Day, and the Netting Member would have also been required to deliver the $110 million on that Business Day to FICC. However, after net-of-net implementation, on the second Business Day, FICC's return of $100 million to the Netting Member is netted against the Netting Member's obligation to deliver $110 million to FICC, such that the Netting Member is only required to deliver the additional $10 million to FICC.

The net-of-net settlement process was implemented by the clearing banks in 2014–2015 and it became FICC's practice at that time. Thus, FICC is proposing to revise the references in Rule 20 to accurately reflect the net-of-net settlement process.

Some of the proposed rule changes necessary to reflect the net-of-net settlement process have already been discussed above. In addition to the changes in this regard discussed above, FICC is proposing to delete the "Day 1/Day 2" terminology in Section 3 of GSD Rule 20, delete terminology pertaining to "reversal" of obligations, and insert terminology regarding "netting" of obligations.

(4) Proposed Changes Regarding the Technical Changes

The technical clean-up changes will not affect Netting Members because these changes do not change the meaning of the GSD Rules as they apply to such Members.

iv. Any Significant Problems Known to FICC That Netting Members Are Likely To Have in Complying With the Proposed Rule Change

FICC does not believe that Netting Members will have problems in complying with the proposed rule changes that permanently adopt the 2015 Pilot and the net-of-net settlement process because these changes are already in effect and reflect current practice. In addition, FICC is not aware of any problems that Netting Members have in complying with these provisions today. FICC does not believe that Netting Members will have a problem complying with the technical changes because they do not change the manner in which the Rules apply to such Members.

v. Detailed Description of the Proposed Rule Changes in Exhibit 5

The proposed rule changes are as follows:

(1) Proposed Changes to Rule 1

The term "GCF Collateral Excess Account" means an account established by a GCF Custodian Bank in the name of the Corporation to hold securities it credits to the GCF Securities Account the Corporation establishes for another GCF Clearing Agent Bank.

(2) Proposed Changes to Rule 20 Section 3

(a) References to "Day 1" and "Day 2" are proposed to be replaced with references to "particular" or "next" Business Days in order to accommodate the net-of-net settlement clarification. Additional drafting changes are reflected, where necessary, to add clarity to this change.

(b) A new paragraph has been added to reflect the collateral substitution process.

(c) The second sentence of the fifth paragraph has been moved to the end of the paragraph for ease of reading. This change also necessitates the deletion of the last sentence of the existing paragraph, which reads as follows: "subject to the provisions of the second sentence of this paragraph".

(d) The seventh paragraph has been amended to delete the reference to "the morning of Day 2" and replace such reference with "a particular Business Day at a time established by the Corporation. . . ." This change reflects that the NFE process is no longer in the morning and also further accommodates the net-of-net settlement clarification.

(3) Proposed Change to Rule 20 Section 7

Rule 20 Section 7 is proposed to be amended to reflect the following technical clean-up changes:

(a) The term "Security" has been changed to "security" in order to conform to the use of "security" throughout this section.

(b) The term "GCF Collateral Excess Account" was inadvertently not included in the Rules thus, it is being introduced in this section in order to add clarity. This term is defined in Rule 1 as "the account established by a GCF Custodian Bank in the name of the Corporation to hold securities it credits to the GCF Securities Account the Corporation establishes for another GCF Clearing Bank."

(4) Proposed Changes to the Schedule of GCF Timeframes

The *Schedule of GCF Timeframes* is proposed to be amended as follows:

(a) To delete the 7:30 a.m. deadline for the return of collateral and replace it with a 3:30 p.m. time at which the net-of-net settlement process occurs.

(b) To add the 7:30 a.m. through 2:30 p.m. timeframe for the facilitation of interbank collateral substitutions.

(c) To change the cut-off time for GCF Repo Transaction submission from 3:35 p.m. to 3:00 p.m. and to also make 3:00 p.m. the deadline for Dealer trade affirmation or disaffirmation and to state that all unaffirmed trades will be automatically affirmed by FICC, that FICC will notify banks and Dealers of final positions and that collateral allocations begin.

(d) To delete the 3:45 p.m. deadline (all of whose processes are now referenced at the 3:00 p.m. timeframe).

2. Statutory Basis

This proposed rule change is designed to: (1) Permanently adopt the rules in the 2015 Pilot Program; (2) incorporate language into the GSD Rules to reflect the net-of-net settlement process; and (3) make technical changes to the GSD Rules. The 2015 Pilot Program has already been approved by the Commission as consistent with the Act.[28] The rules adopted in the 2015 Pilot Program were intended to advance the TPR's Tri-Party Reform recommendations to make the tri-party repo industry safer by moving the morning unwind process to the afternoon in an effort to ensure that such transactions are collateralized all day, thereby limiting the amount of intraday credit that is extended by clearing banks during the day. Permanently adopting these rules will serve to minimize systemic risk and bring certainty to market participants. Accordingly, the permanent adoption the 2015 Pilot Program rules will help to protect investors and the public interest, and help to assure the safeguarding of securities and funds which are in FICC's custody or control or for which FICC is responsible, consistent with Section 17A(b)(3)(F) of the Exchange Act.[29] Permanently adopting these rules will also avoid the need for FICC to renew the pilot program annually.

Codifying the net-of-net settlement process in the GSD Rules constitutes no change to FICC's current operations because the net-of-net settlement process was implemented by the clearing banks in 2014–2015. Changing the GSD Rules to reflect the net-of-net settlement process will eliminate obsolete language from the GSD Rules. Similarly, the technical changes proposed in this filing will make non-substantive corrections that will clarify the GSD Rules. Accordingly, the changes related to the net-of-net settlement process and the technical changes to the GSD Rules will provide for a more well-founded and transparent legal framework for FICC's activities, consistent with Exchange Act Rule 17Ad–22(d)(1).[30]

(B) Clearing Agency's Statement on Burden on Competition

FICC does not believe that the proposed rule change would impose any burden on competition. The proposed changes apply to all Netting Members participating in the GCF Repo service and reflect industry reform efforts that apply to similar transactions outside of FICC.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments on the proposed rule change have not yet been solicited or received. FICC will notify the Commission of any written comments received by FICC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change; or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*) or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–FICC–2016–001 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–FICC–2016–001. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings also will be available for inspection and copying at the principal office of FICC and on FICC's Web site at *http://www.dtcc.com/legal/sec-rule-filings.aspx.*

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[28] Securities Exchange Act Release No. 34–75258 (June 22, 2015), 80 FR 36879 (June 26, 2015) (SR–FICC–2015–002); 15 U.S.C. 78a *et seq.*

[29] 15 U.S.C. 78q–1(b)(3)(F).

[30] 17 CFR 240.17Ad–22(d)(1).

All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FICC–2016–001 and should be submitted on or before May 18, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

Brent J. Fields,

Secretary.

[FR Doc. 2016–09718 Filed 4–26–16; 8:45 am]

BILLING CODE 8011–01–P

SOCIAL SECURITY ADMINISTRATION

[Docket No: SSA–2016–0018]

Agency Information Collection Activities: Proposed Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes a new information collection and a revision of an OMB-approved information collection.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB) Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974, Email address: *OIRA_Submission@omb.eop.gov*

(SSA) Social Security Administration, OLCA, Attn: Reports Clearance Director, 3100 West High Rise, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–966–2830, Email address: *OR.Reports.Clearance@ssa.gov*

Or you may submit your comments online through *www.regulations.gov,* referencing Docket ID Number [SSA–2016–0018].

I. The information collections below are pending at SSA. SSA will submit them to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than June 27, 2016. Individuals can obtain copies of the collection instruments by writing to the above email address.

1. Report of Adult Functioning-Employer—20 CFR 404.1512 and 20 CFR 416.912—0960—NEW. Section 205(a), 223(d)(5)(A), 1631(d)(1), and 1631(e)(1) of the Social Security Act (Act) require claimants applying for Social Security Disability Insurance (SSDI) or Supplemental Security Income (SSI) benefits to provide SSA with medical and other evidence of their disability. 20 CFR 404.1512 and 20 CFR 416.912 of the Code of Federal Regulations provides detailed requirements of the types of evidence Social Security disability claimants and beneficiaries must provide showing how their impairment(s) affects their ability to work (*e.g.,* evidence of age, education and training, work experience, daily activities, efforts to work, and any other evidence). Past employers familiar with the claimant's ability to perform work activities complete Form SSA–385–BK, Report of Adult Functioning-Employer to provide SSA with information about the employees day-to-day functioning in the work setting. SSA and Disability Determination Services use the information Form SSA–3385–BK collects as the basis to determine eligibility or continued eligibility for disability benefits. The respondents are claimants' past employers.

Type of Request: This is a new information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
SSA–3385–BK	3,900	1	20	1,300

2. Work Incentives Planning and Assistance Program—0960–0629. As part of SSA's strategy to assist SSDI beneficiaries and SSI recipients who wish to return to work and achieve self-sufficiency, SSA established the Work Incentives Planning and Assistance (WIPA) program. This community based, work incentive, planning and assistance project collects identifying claimant information via project sites and community work incentives coordinators (CWIC). SSA uses this information to ensure proper management of the project, with particular emphasis on administration, budgeting, and training. In addition, project sites and CWIC's collect data from SSDI beneficiaries and SSI recipients on background employment, training, benefits, and work incentives. SSA is interested in identifying SSDI beneficiary and SSI recipient outcomes under the WIPA program, to determine the extent to which beneficiaries with disabilities and SSI recipients achieve their employment, financial, and healthcare goals. SSA will also use the data in its analysis for future planning for SSDI and SSI programs. Respondents are SSDI beneficiaries, SSI recipients, community project sites, and employment advisors.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
Small WIPA Site (under 150 beneficiaries served)	4,800	1	20	1,600
Medium WIPA Site (150–599 beneficiaries served)	7,500	1	20	2,500

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[31] 17 CFR 200.30–3(a)(12).

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)
Large WIPA Site (600 or more beneficiaries served)	17,700	1	20	5,900
Total WIPA Sites	30,000	....	....	10,000
SSDI & SSI Beneficiaries	30,000	1	25	12,500
Help Line	30,000	1	5	2,500
Total	60,000	....	....	15,000
Grand Total	90,000	....	....	25,000

Dated: April 22, 2016.

Naomi R. Sipple,

Reports Clearance Officer, Social Security Administration.

[FR Doc. 2016–09828 Filed 4–26–16; 8:45 am]

BILLING CODE 4191–02–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36020]

Norfolk Southern Railway Company—Trackage Rights Exemption—Southern Electric Railroad Company

Southern Electric Railroad Company (SERC), pursuant to a written trackage rights agreement,[1] has agreed to grant Norfolk Southern Railway Company (NS) restricted overhead trackage rights over SERC's mainline, between milepost 0.0 and milepost 0.6 in the vicinity of Jefferson County, Ala., a distance of approximately 0.6 miles.

The transaction may be consummated on May 11, 2016, the effective date of the exemption (30 days after the exemption was filed).

NS states that the proposed trackage rights will allow NS to access four private storage tracks (APC Storage Yard) to serve the James H. Miller, Jr. Electric Generating Plant owned by Alabama Power Company near West Jefferson, in Jefferson County, Ala.

As a condition to this exemption, any employees affected by the trackage rights will be protected by the conditions imposed in *Norfolk & Western Railway—Trackage Rights—Burlington Northern, Inc.*, 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Railway—Lease & Operate—California Western Railroad*, 360 I.C.C. 653 (1980).

This notice is filed under 49 CFR 1180.2(d)(7). If the notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed by May 4, 2016 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 36020, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Aarthy S. Thamodaran, Norfolk Southern Corporation, Three Commercial Place, Norfolk, VA 23510.

According to NS, this action is categorically excluded from environmental review under 49 CFR 1105.6(c).

Board decisions and notices are available on our Web site at "*WWW.STB.DOT.GOV.*"

Decided: April 22, 2016.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Tia Delano,

Clearance Clerk.

[FR Doc. 2016–09815 Filed 4–26–16; 8:45 am]

BILLING CODE 4915–01–P

[1] A redacted version of the draft trackage rights agreement between SERC and NS was filed with the notice. NS states that an unredacted version of the agreement will be provided to any requesting party upon the issuance by the Board of an appropriate protective order. NS also states that it will submit an executed copy of the agreement within 10 days of its execution, pursuant to 49 CFR 1180.6(a)(7)(ii).

SURFACE TRANSPORTATION BOARD

[Docket No. AB 55 (Sub-No. 756X)]

CSX Transportation, Inc.—Discontinuance of Service Exemption—in Letcher County, KY

CSX Transportation, Inc. (CSXT), filed a verified notice of exemption under 49 CFR part 1152 subpart F—*Exempt Abandonments and Discontinuances of Service* to discontinue service over an approximately 1.17-mile line of railroad (the Line), on its Southern Region, Huntington Division, Rockhouse Subdivision, Engineering Appalachian Division (also known as the Pat Kentucky Wye), from mileposts 0VM 280.36 and 0VM1 280.39 to milepost 0VM 281.32 in Camp Branch, Letcher County, KY.[1] The Line traverses United States Postal Service Zip Code 41858.

CSXT has certified that: (1) No local traffic has moved over the Line for at least two years; (2) there is no overhead traffic on the Line; (3) no formal complaint filed by a user of rail service on the Line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the Line either is pending before the Surface Transportation Board or any U.S. District Court or has been decided in favor of a complainant within the two-year period; and (4) the requirements at 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the discontinuance shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho*, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) to subsidize continued rail service has been received, this exemption will become effective on May 27, 2016 (50 days after the filing of the exemption), unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues and formal expressions of intent to file an OFA to subsidize continued rail service under 49 CFR 1152.27(c)(2)[2] must be filed by May 9, 2016.[3] Petitions to reopen must be filed by May 17, 2016, with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001.

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[1] CSXT states there is one station on the Line, Sapphire, at milepost 0VM 281.0 (FSAC 42918/ OPSL 17470).

[2] Each OFA must be accompanied by the filing fee, which is currently set at $1,600. *See* 49 CFR 1002.2(f)(25).

A copy of any petition filed with the Board should be sent to CSXT's representative: Louis E. Gitomer, 600 Baltimore Ave., Suite 301, Towson, MD 21204.

If the verified notice contains false or misleading information, the exemption is void ab initio.

Because there will be an environmental review during an abandonment, this discontinuance does not require an environmental review.

Board decisions and notices are available on our Web site at *WWW.STB.DOT.GOV.*

Decided: April 21, 2016.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2016–09819 Filed 4–26–16; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2016–56]

Petition for Exemption; Summary of Petition Received; O'Connor Aerial Videos Editing LLC

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Title 14 of the Code of Federal Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before May 17, 2016.

ADDRESSES: Send comments identified by docket number FAA–2015–1928 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Dan Ngo, (202) 267–4264, 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on April 21, 2016.

James M. Crotty,

Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2015–1928.

Petitioner: O'Connor Aerial Videos Editing LLC.

Section(s) of 14 CFR Affected: §§ 61.53 and 61.56.

Description of Relief Sought: The petitioner is seeking to amend Exemption No. 12236 by requesting relief from the licensed pilot requirement and the flight review requirement in 14 CFR 61.53 (Condition 13), as well as relief from requiring a VO during operations, as indicated in Condition 6.

[FR Doc. 2016–09778 Filed 4–26–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2016–46]

Petition for Exemption; Summary of Petition Received; Aviation Systems Engineering Company

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Title 14 of the Code of Federal Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before May 17, 2016.

ADDRESSES: Send comments identified by docket number FAA–2015–0481 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the

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[3] Because this is a discontinuance proceeding and not an abandonment, interim trail use/rail banking and public use conditions are not appropriate.

West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Dan Ngo, 202–267–4264 800 Independence Avenue SW., Washington, DC 20591. This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on April 21, 2016.

James M. Crotty,

Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2015–0481.

Petitioner: Aviation Systems Engineering Company.

Section(s) of 14 CFR Affected: §§ 91.119(c) and 91.151(a)(1).

Description of Relief Sought: The petitioner is seeking relief to amend Exemption No. 11509 to operate within 500 feet from nonparticipating persons, as well as relief from the minimum fuel requirement.

[FR Doc. 2016–09779 Filed 4–26–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2016–49]

Petition for Exemption; Summary of Petition Received; VT DRB Aviation Consultants

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Title 14 of the Code of Federal Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before May 17, 2016.

ADDRESSES: Send comments identified by docket number FAA–2015–8751 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Deana Stedman, ANM–113, Federal Aviation Administration, 1601 Lind Avenue SW., Renton, WA 98057–3356, email *deana.stedman@faa.gov,* phone (425) 227–2148.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on April 20, 2016.

James M. Crotty,

Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2015–8751.

Petitioner: VT DRB Aviation Consultants.

Section(s) of 14 CFR Affected: § 25.817.

Description of Relief Sought: VT DRB Aviation Consultants petitions the FAA for an exemption from § 25.817 which allows no more than three seats abreast on each side of the aisle in any one row. Instead, the petitioner wishes to install four seats abreast on one side of the aisle with no seats on the opposite side, having less passenger egress impedance than in standard Boeing Model 777 passenger jet configurations.

[FR Doc. 2016–09773 Filed 4–26–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Aviation Rulemaking Advisory Committee—New Task

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of a new task assignment for the Aviation Rulemaking Advisory Committee.

SUMMARY: The FAA assigned the Aviation Rulemaking Advisory Committee (ARAC) a new task to provide recommendations regarding bird strike protection rulemaking, policy, and guidance for normal category rotorcraft and to provide recommendations to enhance the existing bird strike protection standards for transport category rotorcraft. The FAA amended its regulations to incorporate bird strike protection rules for transport category rotorcraft in 1996. Data shows an increase in the bird population and weight has resulted in an increase in bird strikes with both normal category rotorcraft and transport category rotorcraft. The increase in bird strikes has led to more frequent bird penetration into the cockpit and cabin areas, elevating the risk of potential serious injuries or fatalities to occupants. Direct bird impact to the pilot has led to partial or complete pilot incapacitation in numerous cases, increasing the risk of fatalities.

This notice informs the public of the new ARAC activity and solicits membership for the Rotorcraft Bird Strike Working Group.

FOR FURTHER INFORMATION CONTACT: Gary B. Roach, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177, *Gary.B.Roach@faa.gov,* phone number 817–222–5110, facsimile number 817–222–5961.

SUPPLEMENTARY INFORMATION:

ARAC Acceptance of Task

As a result of the March 23, 2016, ARAC meeting, the FAA assigned and ARAC accepted this task establishing the Rotorcraft Bird Strike Working Group. The Rotorcraft Bird Strike Working Group will serve as staff to the ARAC and provide advice and recommendations on the assigned task. The ARAC will review and accept the recommendation report and will submit it to the FAA.

Background

The FAA established the ARAC to provide information, advice, and recommendations on aviation-related issues that could result in rulemaking, to the FAA Administrator, through the Associate Administrator of Aviation Safety.

In 1996, a bird strike protection rule (14 CFR 29.631) was adopted requiring that transport category rotorcraft be designed to ensure continued safe flight and landing (for Category A) or safe landing (for Category B) following an impact with a 2.2-pound bird. At that time, bird strike protection was not adopted for normal category rotorcraft. As of 2015, normal category rotorcraft comprise over 90% of rotorcraft operating in the U.S. The data from the FAA's Wildlife Strike Database indicates about 75% of reported bird strikes from 1990–2013 were with normal category rotorcraft. These percentages suggest that the absence of bird strike protective requirements for normal category rotorcraft results in increased risk for the majority of U.S. rotorcraft.

Further analysis of rotorcraft data from the FAA's Wildlife Strike Database indicates a 68% increase in bird strikes since 2009 and more than a 700% increase since the early 2000s. In raw numbers, the percentages translate from around 25 reports of rotorcraft bird strikes per year in the early 2000s, to 121 strikes in 2009, to 204 strikes in 2013. Using rotorcraft flight hours to perform a rate-based analysis, reported bird strikes increased 49% in the five year period from 2010 to 2014 (3.99 per 100,000 flight hours to 5.95 per 100,000 flight hours). Better event reporting accounts for some of this increase, but the rapid escalation goes beyond reporting improvements alone. One conjecture is the increase may be caused by the growing population of birds in general, a growing population of larger birds, quieter aircraft, and an increase in the number of rotorcraft operations.

In addition to the increased frequency of bird strikes, the FAA has observed increased strikes to the rotorcraft windscreen area with a force of impact that has directly endangered occupants and elevated the risk to safe rotorcraft operations. Bird penetration into the cockpit and cabin areas has become increasingly common, elevating the probability of potential serious injuries or fatalities to occupants. Moreover, direct bird impact to the pilot has led to partial or complete pilot incapacitation in numerous cases, often causing an increased risk for loss of control of the rotorcraft and fatalities. The typical scenario is that the bird strikes and shatters a portion of the front windscreen. The bird's remains, as well as damaged portions of the rotorcraft (such as the windscreen), either hit the pilot in the head, neck, or upper torso, or proceed through the cockpit to strike the passengers or crew.

These recent observations reinforce previous findings from the study, *Bird Strikes to Civil Helicopters in the United States, 1990–2005* (2006), by Cleary, Dolbeer, and Wright, based on 15 years of data from the FAA's National Wildlife Database. The study concluded that: (1) Helicopters were significantly more likely to be damaged by bird strikes than airplanes, (2) windshields on helicopters were more frequently struck and damaged than windshields on airplanes, and (3) helicopter bird strikes were more likely to lead to injuries to crew or passengers than airplane bird strikes. The NTSB referenced these same findings in its accident report of a 2009 fatal rotorcraft accident in Morgan City, LA, where a bird strike was determined to be the probable cause of the accident (NTSB Aircraft Accident Report No. CEN09MA117).

Some bird strike events where the bird penetrates the cockpit and cabin have received less attention either because the damage was limited to the windscreen or because the injury to the crew and passengers was minor. However, a superficial examination of the rotorcraft damage and occupant injury levels is misleading. The FAA has found that most of these cases had less to do with the sufficiency of aircraft design and equipage, and more to do with the crew's personal protective gear—such as helmets—that mitigated the potential event severity. Other cases of low severity are the result of fortuitous circumstance. One specific example occurred during a March 2015 police operation in Dallas, Texas, where a bird penetrated the cockpit and struck the pilot, who was not wearing a helmet. The pilot was incapacitated by the impact and—under ordinary circumstances—the event would likely have led to a fatal outcome from loss of rotorcraft control. However, the left seat occupant happened to be a rated helicopter pilot, something that was not typical for the police operation being conducted. The left seat occupant then assumed control of the rotorcraft and landed without incident. The result was an event with a low-severity outcome, but the underlying lesson from the relatively benign consequence cannot be dismissed.

While the absence of any bird strike requirements for normal category rotorcraft must be addressed, data shows that bird strikes with transport category rotorcraft are a growing concern, especially encounters with larger birds. Transport category rotorcraft are more likely to spend extended time in the en route phase of flight and fly at higher altitudes. While the higher altitude would appear to reduce the probability of encountering bird strike, data shows an increased altitude does not mitigate the severity of damage when a bird strike occurs. A United States Department of Agriculture (USDA) study found that, of the 32 damaging strikes that occurred to U.S. rotorcraft in 2014, 72% of those occurred *more than* 500 feet above ground level. The study opined that the more severe damage was likely attributable to the higher speed of the rotorcraft during the en route phase of flight. The increased exposure of transport category rotorcraft in this environment suggests the existing 2.2-pound bird strike requirement may not be adequate.

Whether normal category or transport category, the unique operating profile of a helicopter leads to a different exposure to bird strike risk than does fixed-wing aircraft. The study, *Wildlife strikes to civil helicopters in the U.S., 1990–2011* (2013) by Washburn, Cisar, and Default, discusses some of the differences. It concluded that, unlike with fixed-wing aircraft, helicopter bird strikes occur with greatest frequency during the en route phase of flight and in the off-airfield environment. It credits bird strikes that occur in the off-airfield environment as accounting for the majority of bird strike-related human injuries and fatalities for helicopters. Since helicopters operate at much lower altitudes than fixed-wing aircraft, the exposure to the risk of a bird strike is not limited to the departure and arrival phases of flight, but instead remains for the duration of the flight profile.

The Task

The Rotorcraft Bird Strike Working Group will provide advice and recommendations to the ARAC on bird strike protection rulemaking, policy, and guidance for parts 27 and 29. The Rotorcraft Bird Strike Working Group is tasked to:

1. For normal category rotorcraft, specifically advise and make written recommendations on how to incorporate bird strike protection requirements into the part 27 airworthiness standards for newly type certificated rotorcraft.
2. For normal category rotorcraft, specifically advise and make written recommendations on how the bird strike protection requirements in Task 1 should be made effective via § 27.2 for newly manufactured rotorcraft.
3. For transport category rotorcraft, specifically advise and make written recommendations on how to enhance

the § 29.631 bird strike protection airworthiness standard in light of increases in bird weight and increased exposure to bird strikes for newly type certificated rotorcraft.

4. For transport category rotorcraft, specifically advise and make written recommendations on how the bird strike protection requirements in Task 3 should be made effective via § 29.2 for newly manufactured rotorcraft.

5. For normal and transport category rotorcraft, specifically advise and make written recommendations on incorporating rotorcraft bird strike protection improvements and standards into the existing rotorcraft fleet.

6. For Tasks 1 through 5, consider existing non-traditional bird strike protection technology, including the use of aircraft flight manual limitations (such as requiring airspeed limitations at lower altitudes), when making the recommendations. These considerations must include: An evaluation of the effectiveness of such technology, assumptions used as part of that evaluation, validation of those assumptions, and any procedures to be used for operation with the technology or with the aircraft limitations.

7. Based on the recommendations in Tasks 1 through 6, specifically advise and make written recommendations for the associated policy and guidance.

8. Based on the Rotorcraft Bird Strike Working Group recommendations, perform the following:

a. Estimate what the regulated parties would do differently as a result of the proposed recommendation and how much it would cost.

b. Estimate the safety improvements of future bird encounters from the proposed recommendations.

c. Estimate any other benefits (*e.g.,* reduced administrative burden) or costs that would result from implementation of the recommendations.

9. Develop a report containing recommendations on the findings and results of the tasks explained above. The report should document:

a. Both majority and dissenting positions on the findings and the rationale for each position.

b. Any disagreements, including the rationale for each position and the reasons for the disagreement.

10. The working group may be reinstated to assist the ARAC in responding to the FAA's questions or concerns after the recommendation report has been submitted.

Schedule

The recommendation report should be submitted to the FAA for review and acceptance no later than 18 months after publication of this notice in the **Federal Register**.

Working Group Activity

The Rotorcraft Bird Strike Working Group must comply with the procedures adopted by the ARAC as follows:

1. Conduct a review and analysis of the assigned tasks and any other related materials or documents.

2. Draft and submit a work plan for completion of the task, including the rationale supporting such a plan, for consideration by the ARAC.

3. Provide a status report at each ARAC meeting.

4. Draft and submit the recommendation report based on review and analysis of the assigned tasks.

5. Present the recommendation report at the ARAC meeting.

Participation in the Working Group

The Rotorcraft Bird Strike Working Group will be comprised of technical experts having an interest in the assigned task. A working group member need not be a member representative of the ARAC. The FAA would like a wide range of members (normal category rotorcraft manufacturers, transport category rotorcraft manufacturers, and rotorcraft operators from various segments of the industry such as oil and gas exploration, emergency medical services, and air tour operators) to ensure all aspects of the tasks are considered in development of the recommendations. The provisions of the August 13, 2014, Office of Management and Budget guidance, "Revised Guidance on Appointment of Lobbyists to Federal Advisory Committees, Boards, and Commissions" (79 FR 47482), continues the ban on registered lobbyists participating on Agency Boards and Commissions if participating in their "individual capacity." The revised guidance now allows registered lobbyists to participate on Agency Boards and Commissions in a "representative capacity" for the "express purpose of providing a committee with the views of a nongovernmental entity, a recognizable group of persons or nongovernmental entities (an industry, sector, labor unions, or environmental groups, etc.) or state or local government." (For further information, see Lobbying Disclosure Act of 1995 as amended, 2 U.S.C. 1603, 1604, and 1605.)

If you wish to become a member of the Rotorcraft Bird Strike Working Group, write the person listed under the caption **FOR FURTHER INFORMATION CONTACT** expressing that desire. Describe your interest in the task and state the expertise you would bring to the working group. The FAA must receive all requests by May 27, 2016. The ARAC and the FAA will review the requests and advise you whether or not your request is approved.

If you are chosen for membership in the working group, you must actively participate in the working group, attend all meetings, and provide written comments when requested. You must devote the resources necessary to support the working group in meeting any assigned deadlines. You must keep your management and those you may represent advised of working group activities and decisions to ensure the proposed technical solutions do not conflict with the position of those you represent. Once the working group has begun deliberations, members will not be added or substituted without the approval of the ARAC Chair, the FAA, including the Designated Federal Officer, and the Working Group Chair.

The Secretary of Transportation determined the formation and use of the ARAC is necessary and in the public interest in connection with the performance of duties imposed on the FAA by law.

The ARAC meetings are open to the public. However, meetings of the Rotorcraft Bird Strike Working Group are not open to the public, except to the extent individuals with an interest and expertise are selected to participate. The FAA will make no public announcement of working group meetings.

Issued in Washington, DC, on April 19, 2016.

Lirio Liu,

Designated Federal Officer, Aviation Rulemaking Advisory Committee.

[FR Doc. 2016–09781 Filed 4–26–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2016–59]

Petition for Exemption; Summary of Petition Received; Bombardier Aerospace

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Title 14 of the Code of Federal Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before May 9, 2016.

ADDRESSES: Send comments identified by docket number FAA–2016–4198 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Deana Stedman, Federal Aviation Administration, ANM–113, 1601 Lind Avenue SW., Renton, WA 98057–3356, email *deana.stedman@faa.gov,* phone (425) 227–2148.This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on April 15, 2016.

Dale Bouffiou,

Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2016–4198.

Petitioner: Bombardier Aerospace.

Section(s) of 14 CFR Affected: § 25.981(a)(3).

Description of Relief Sought: Bombardier Aerospace requests time-limited relief from the requirements of 14 CFR 25.981(a)(3) as it relates to the fuel boost pump design of the Model BD–500–1A10 and BD–500–1A11 airplanes. Relief would be for a period of 3 years after FAA type validation to incorporate necessary design changes into production.

[FR Doc. 2016–09775 Filed 4–26–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2016–55]

Petition for Exemption; Summary of Petition Received; Trumbull Unmanned LLC

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Title 14 of the Code of Federal Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before May 17, 2016.

ADDRESSES: Send comments identified by docket number FAA–2014–0890 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Dan Ngo, (202) 267–4264 800 Independence Avenue SW., Washington, DC 20591. This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on April 21, 2016.

James M. Crotty,

Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2014–0890.

Petitioner: Trumbull Unmanned LLC.

Section(s) of 14 CFR Affected: 61.113 (a) and (b); 91.109; 91.119 (c); 91.121; 91.151 (a); 91.405 (a); 91.407 (a) (1); 91.409 (a)(2); 91.417 (a) and (b).

Description of Relief Sought: The petitioner is requesting an amendment to Exemption No. 11146 for relief in order to operate UAS from a moving vehicle and to operate the Lockheed Martin Stalker XE UAS powered by a hybrid power system utilizing a solid oxide propane fuel cell.

[FR Doc. 2016–09780 Filed 4–26–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2016–58]

Petition for Exemption; Summary of Petition Received; Bombardier Aerospace

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Title 14 of the Code of Federal Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor

the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before May 9, 2016.

ADDRESSES: Send comments identified by docket number FAA–2016–2750 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Deana Stedman, Federal Aviation Administration, ANM–113, 1601 Lind Avenue SW., Renton, WA 98057–3356, email *deana.stedman@faa.gov,* phone (425) 227–2148. This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on April 15, 2016.

Dale Bouffiou,

Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2016–2750.

Petitioner: Bombardier Aerospace.

Section(s) of 14 CFR Affected: § 25.901(c).

Description of Relief Sought: Bombardier Aerospace requests relief from the requirements of 14 CFR 25.901(c) as it relates to potential single failures within the throttle quadrant assembly of the Model BD–500–1A10 and BD–500–1A11 airplanes that could result in an engine uncontrolled high thrust event. Such an event can be catastrophic under certain takeoff and landing scenarios.

[FR Doc. 2016–09774 Filed 4–26–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2016–61]

Petition for Exemption; Summary of Petition Received: Airbus SAS

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number involved and must be received on or before May 9, 2016.

ADDRESSES: You may send comments identified by Docket Number FAA–2016–6120 using any of the following methods:

- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.
- *Fax:* Fax comments to the Docket Management Facility at 202–493–2251.
- *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Docket: To read background documents or comments received, go to *http://www.regulations.gov* at any time or to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Sandra Long, ARM–200, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591, phone (202) 493–5245, email *sandra.long@faa.gov.*

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on April 20, 2016.

James M. Crotty,

Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2016–6120.

Petitioner: Airbus SAS.

Section of 14 CFR Affected: 14 CFR 25.865, 25.901(c), 25.1181, and 25.1191.

Description of Relief Sought: Airbus seeks time-limited relief from the requirements for fire protection of flight controls, engine mounts, and other flight structure; and designated fire zones and firewalls.

[FR Doc. 2016–09771 Filed 4–26–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2016–54]

Petition for Exemption; Summary of Petition Received; Aerial Net

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Title 14 of the Code of Federal Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process.

Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before May 17, 2016.

ADDRESSES: Send comments identified by docket number FAA–2015–3133 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Dan Ngo, (202) 267–4264, 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on April 21, 2016.

James M. Crotty,

Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2015–3133.

Petitioner: Aerial Net.

Section(s) of 14 CFR Affected: Part 21; 45.23(b); 61.113(a) & (b); 61.133(a); 91.7(a); 91.9(b)(2) & (c); 91.103; 91.109(a); 91.119; 91.121; 91.151(a); 91.203(a) & (b); 91.405(a); 91.407(a)(1); 91.409(a)(2); 91.417(a).

Description of Relief Sought: The petitioner is requesting to use the Vario XLC V2 Helicopter, which is a turbine-powered helicopter with a maximum takeoff weight of 32kg.

[FR Doc. 2016–09777 Filed 4–26–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2016–51]

Petition for Exemption; Summary of Petition Received; Delta Air Lines, Inc.

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Title 14 of the Code of Federal Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before May 17, 2016.

ADDRESSES: Send comments identified by docket number FAA–2016–5244 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this action, contact Nia Daniels, 800 Independence Avenue SW., Washington, DC 20519, (202) 267–7626.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on April 21, 2016.

Jim Crotty,

Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2016–5244.

Petitioner: Delta Air Lines, Inc.

Section of 14 CFR Affected: 121.339(c).

Description of Relief Sought: Delta Air Lines, Inc. petitioned for an exemption to operate the Airbus A319/A320/A321 aircraft with the survival kits remotely stowed from the slide/rafts.

[FR Doc. 2016–09776 Filed 4–26–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2016–0102]

Broker and Freight Forwarder Financial Responsibility Roundtable

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of meeting, request for public comment.

SUMMARY: FMCSA announces that it will host an informal roundtable discussion pertaining to property broker and freight forwarder financial responsibility. The meeting will focus on the adequacy of existing trust fund industry practices, Federal requirements for such institutions, and the underlying instruments they issue for use by brokers and freight forwarders submitting the Broker's or Freight Forwarder's Trust Fund Agreement (FMCSA Form BMC–85) to satisfy the

Agency's financial responsibility rules. The Agency seeks information from motor carriers and shippers that have experienced challenges receiving compensation for claims against freight forwarders and brokers due to insufficient funds. The meeting will be public. Individuals with diverse experience, expertise, and perspectives are encouraged to attend. This meeting does not pertain to increasing motor carrier, broker, or freight forwarder minimum financial responsibility limits. If all comments have been exhausted prior to the end of the session, the session may conclude early.

DATES: The roundtable discussion will be held on Friday, May 20, 2016, from 9:30 a.m. to 4:30 p.m., Eastern Time (ET) at the U. S. Department of Transportation, Media Center, 1200 New Jersey Avenue SE., Ground Floor, Washington, DC 20590. The entire proceedings will be public.

ADDRESSES: You may submit comments bearing the Federal Docket Management System Docket ID (FMCSA–2016–0102) using any of the following methods:

Federal eRulemaking Portal: Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.

Mail: Docket Management Facility: U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.

Hand Delivery or Courier: West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays.

Fax: 1–202–493–2251.

Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received without change to *www.regulations.gov,* including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to *www.regulations.gov* at any time or visit Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The online Federal document management system is available 24 hours each day, 365 days each year. If you would like acknowledgment that the Agency received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments online. The docket FMCSA–2016–0102 will remain open indefinitely.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

FOR FURTHER INFORMATION CONTACT: *For information concerning this notice,* contact Dr. Gerald Folsom, Office of Registration and Safety Information, (202) 385–2405, or by email at *Gerald.folsom@dot.gov.*

For information about the public meeting: Ms. Shannon L. Watson, Senior Policy Advisor, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590, by telephone at 202–366–2551, or by email at *Shannon.Watson@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Docket Services at 202–366–9826. Business hours are from 8:00 a.m. to 4:30 p.m. ET, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages participation in the roundtable discussion and the submission of comments and related materials. Documents for discussion at the meeting should be submitted to the docket at least 7 business days in advance of the meeting.

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2016–0102), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these methods. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov* and put the docket number, "FMCSA–2016–0102" in the "Keyword" box and click "Search." When the new screen appears, click on the "Comment Now!" button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

Confidential Business Information

Confidential Business Information (CBI) is commercial or financial information that is customarily not made available to the general public by the submitter. Under the Freedom of Information Act, CBI is eligible for protection from public disclosure. If you have CBI that is relevant or responsive to this Notice, it is important that you clearly designate the submitted comments as CBI. Accordingly, please mark each page of your submission as "confidential" or "CBI." Submissions designated as CBI and meeting the definition noted above will not be placed in the public docket of this Notice. Submissions containing CBI should be sent to Mr. Brian Dahlin, Chief, Regulatory Analysis Division, 1200 New Jersey Avenue SE., Washington, DC 20590. Any commentary that FMCSA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

FMCSA will consider all comments and materials received during the comment period.

B. Viewing Comments and Documents

To view comments, go to *http://www.regulations.gov* and insert the docket number, "FMCSA–2016–0102" in the "Keyword" box and click "Search." Next, click the "Open Docket Folder" button and choose the document listed to review. If you do not have access to the internet, you may view the docket by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

II. Background

MAP–21 Section 32918

In the Moving Ahead for Progress in the 21st Century Act (MAP–21) (Pub. L. 112–141), Congress enacted Section 32918, Financial Security of Brokers and Freight Forwarders. Section 32918 raised the financial security amount for brokers to $75,000 and extended the financial security requirement to freight forwarders for the first time. FMCSA implemented those requirements in a 2013 Omnibus rulemaking (78 FR 60226) (Oct. 1, 2013), codified at 49 CFR 387.307(a) (brokers) and 49 CFR 387.403(c) and 387.405 (freight forwarders). Brokers or Freight Forwarders are required to have either a BMC–84 Surety Bond or BMC–85 trust fund on file with the Agency as a condition of obtaining FMCSA operating authority.

MAP–21 added requirements pertaining to the composition of trust fund assets (49 U.S.C. 13906(b)(1)(C),(c)(1)(D)), the immediate suspension of broker or freight forwarder operating authority if their financial security falls below $75,000 (49 U.S.C. 13906(b)(5),(c)(6)), and the payment of claims in the event of financial failure or insolvency (49 U.S.C. 13906(b)(6),(c)(7)). Additionally, it gave FMCSA the authority to take direct enforcement action against surety providers, either through administrative proceedings, court action or suspending their ability to make financial security filings with the agency. (49 U.S.C. 13906(b)(7),(c)(8)).

Since MAP–21's enactment, various parties have filed numerous complaints with the agency pertaining to BMC–85 trust fund providers. Multiple entities have sought guidance from the Agency, pertaining to the portions of section 32918 not covered in the omnibus rule, particularly regarding procedures to be followed in connection with the insolvency or financial failure of a broker.

As an agency whose primary mission is to promote motor carrier safety, 49 U.S.C. 113(c), FMCSA requests additional input from stakeholders in connection with broker/freight forwarder financial security. The Agency seeks to ensure that shippers and motor carriers can collect on the required broker/freight forwarder financial instruments and that appropriate guidance on section 32918 is available to interested parties while avoiding the diversion of Agency resources from critical safety functions. The Agency believes that this roundtable discussion will help gather critical information on how to best meet its responsibilities pursuant to section 32918.

FMCSA seeks attendance or participation by all interested parties at the roundtable discussion, including but not limited to, various aspects of the brokerage and freight forwarding industries (including small business segments of the industry and their representatives), motor carriers (including the household goods industry), shippers, owner-operators, the surety bond industry, BMC–85 trust fund filers, groups representing small businesses, state regulators of loan and finance companies and insurance companies, Federal surety bond regulators and all other interested parties.

As a result of this roundtable discussion, FMCSA hopes to develop a clear path toward implementing fully section 32918 of MAP–21.

Topics for Roundtable Discussion

FMCSA welcomes comments or questions before and during the roundtable discussion. The roundtable will center on the following questions but may be expanded as necessary for a full discussion of the relevant issues:

(1) Which, if any, BMC–85 Trust Fund holders routinely deny claims made by shippers and motor carriers against those trust funds?

(2) What is the nature of the assets that are being held in BMC–85 trust funds and what is the most desirable composition of the assets? For example, should trust funds consist solely of cash or other highly liquid financial instruments? What types of instruments constitute "highly liquid?" Aside from cash, what else can satisfy MAP–21's mandate that trust funds consist of "readily available assets . . . ?" Should the Agency define the classes of investments held in trust relative to risk profile of the issuer and identify the relative liquidity of such assets or should it rely on other sources for such information?

(3) Aside from FMCSA, are BMC–85 trust fund filers being regulated by any other governmental entity? If so, what is the nature of their regulation by state or other authorities?

(4) What actions can FMCSA take to ensure that motor carriers and shippers are able to collect on BMC–85 trust funds where legitimate claims are filed with the financial institution?

(5) Should the Agency act to address potential issues associated with the solvency of BMC–85 trust funds? If so, what type of action would be most appropriate? What type of FMCSA action pertaining to 49 U.S.C. 13906(b)(6) and (c)(7)(payment in cases of financial failure or insolvency) is necessary? Would agency guidance, as opposed to rulemaking, be sufficient?

(6) Should FMCSA require brokers and freight forwarders to demonstrate the creditworthiness of the entity with whom brokers or freight forwarders intend to execute a trust fund, based on a determination of creditworthiness by the applicable state regulatory authority or the Department of Treasury Financial Management Service?

FMCSA will utilize the comments received in advance of the roundtable discussion to further frame the issues.

Accessibility Needs

The U.S. Department of Transportation is committed to providing equal access to the roundtable discussion. If you need special accommodations for the roundtable, such as sign language interpretation, please contact Ms. Shannon L. Watson, Senior Policy Advisor, FMCSA, by telephone at 202–366–2551, at least one week prior to the event to allow us sufficient time to arrange for such services. We will make every attempt to fulfill requested accommodations.

Issued on: April 21, 2016.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2016–09849 Filed 4–26–16; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Petition for Exemption from the Federal Motor Vehicle Theft Prevention Standard; BMW OF NORTH AMERICA, LLC

AGENCY: National Highway Traffic Safety Administration (NHTSA) Department of Transportation (DOT).

ACTION: Grant of petition for exemption.

SUMMARY: This document grants in full the BMW of North America, LLC's (BMW) petition for an exemption of the MINI Countryman multi-purpose passenger vehicle (MPV) line in accordance with 49 CFR part 543, *Exemption from the Theft Prevention Standard.* This petition is granted because the agency has determined that the antitheft device to be placed on the line as standard equipment is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of 49 CFR part 541, *Federal Motor Vehicle Theft Prevention Standard* (Theft Prevention Standard). BMW requested confidential treatment for specific information in its petition that the agency will address by separate letter.

DATES: The exemption granted by this notice is effective beginning with the 2017 model year (MY).

FOR FURTHER INFORMATION CONTACT: Ms. Carlita Ballard, Office of International

Policy, Fuel Economy and Consumer Programs, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., West Building, Room W43–439, Washington, DC 20590. Ms. Ballard's telephone number is (202) 366–5222. Her fax number is (202) 493–2990.

SUPPLEMENTARY INFORMATION: In a petition dated March 25, 2016, BMW requested an exemption from the parts-marking requirements of the Theft Prevention Standard for the MINI Countryman MPV line beginning with MY 2017. The petition requested an exemption from parts-marking pursuant to 49 CFR part 543, *Exemption from Vehicle Theft Prevention Standard,* based on the installation of an antitheft device as standard equipment for the entire vehicle line.

Under 49 CFR part 543.5(a), a manufacturer may petition NHTSA to grant an exemption for one vehicle line per model year. In its petition, BMW provided a detailed description and diagram of the identity, design, and location of the components of the antitheft device for its MINI Countryman MPV line. Key features of the antitheft device will include a key with a transponder, loop antenna (coil), engine control unit (DME/DDE) with encoded start release input, an electronically coded vehicle immobilizer/car access system (EWS/CAS) control unit and a passive immobilizer. BMW stated that its MINI Countryman MPV line will be installed with a passive vehicle immobilizer device as standard equipment. BMW stated that the EWS immobilizer device prevents the vehicle from being driven away under its own engine power and also fulfills the requirements of European vehicle insurance companies. BMW will not offer an audible or visible alarm feature on the proposed device.

BMW's submission is considered a complete petition as required by 49 CFR 543.7, in that it meets the general requirements contained in § 543.5 and the specific content requirements of § 543.6.

In addressing the specific content requirements of Part 543.6, BMW provided information on the reliability and durability of its device. To ensure reliability and durability of the device, BMW conducted tests and believes that the device is reliable and durable because it complied with its own specific standards and is installed on other vehicle lines for which the agency has granted a parts-marking exemption. Further assuring the reliability and durability of the MINI Countryman's antitheft device, BMW stated that the vehicle's mechanical keys are unique because they require a special key blank, cutting machine and a unique vehicle code to allow for key duplication. BMW further stated that the new keys will only be issued to authorized persons and will incorporate special guide-way millings, making the locks almost impossible to pick and the keys impossible to duplicate on the open market.

BMW stated that activation of its immobilizer device occurs automatically when the engine is shut off and the vehicle key is removed from the ignition lock cylinder. Deactivation of the device occurs when the Start/Stop button is pressed and the vehicle starting process begins. BMW stated that deactivation cannot be carried out with a mechanical key, but must occur electronically. Specifically, BMW stated that its transponder sends key data to the EWS/CAS control unit. The correct key data must be recognized by the EWS/CAS control unit in order for the vehicle to start. The transponder contains a chip which is integrated in the key and powered by a battery. The transponder also consists of a transmitter/receiver which communicates with the EWS/CAS control unit. The EWS/CAS control unit provides the interface to the loop antenna (coil), engine control unit and starter. The ignition and fuel supply are only released when a correct coded release signal has been sent by the EWS/CAS control unit to deactivate the device and allow the vehicle to start. When the EWS/CAS control unit has sent a correct release signal, and after the initial starting value, the release signal becomes a rolling, ever-changing, random code that is stored in the DME/DDE and EWS/CAS control units. The DME/DDE must identify the correct release signal to release the ignition signal and fuel supply.

BMW stated that the vehicle is also equipped with a central-locking system that can be operated to lock and unlock all doors or to unlock only the driver's door, thereby preventing forced entry into the vehicle through the passenger doors. The vehicle can be further secured by locking the doors and hood using either the key lock cylinder on the driver's door or the remote frequency remote control. BMW stated that the frequency for the remote control constantly changes to prevent an unauthorized person from opening the vehicle by intercepting the signals of its remote control.

BMW further stated that all of its vehicles are currently equipped with antitheft devices as standard equipment, including its MINI Countryman MPV line. BMW compared the effectiveness of its antitheft device with devices which NHTSA has previously determined to be as effective in reducing and deterring motor vehicle theft as would compliance with the parts-marking requirements of Part 541. Specifically, BMW has installed its antitheft device on its X1 (MPV and passenger cars), X3, X4 and X5 vehicle lines, as well as its Carline 1, 3, 4, 5, 6, 7, Z4, and MINI vehicle lines, all which have been granted parts-marking exemptions by the agency. BMW asserts that theft data have indicated a decline in theft rates for vehicle lines that have been equipped with antitheft devices similar to that which it proposes to install on the MINI Countryman MPV line. BMW also stated that for MY/CY 2011, the agency's data show that theft rates for its lines are: 0.34 (1-series), 0.69 (3-series), 1.26 (5-series), 2.47 (6-series) 1.66 (7-series), 0.24 (X1), 0.68 (X3), 2.02 (Z4), and 0.32 (MINI Cooper). Using an average of 3 MYs data (2011–2013), NHTSA's theft rates for BMW's 1 series, 3 series, 5 series, 6 series, 7 series, X1, X3, Z4 and MINI Cooper vehicle lines are 0.4954, 0.6581, 0.9935, 2.8054, 1.4711, 0.2356, 0.4961, 1.2843 and 0.3385 respectively, all below the median theft rate of 3.5826.

Based on the supporting evidence submitted by BMW, the agency believes that the antitheft device for the BMW MINI Countryman MPV line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard (49 CFR part 541). The agency concludes that the device will provide four of the five types of performance listed in § 543.6(a)(3): Promoting activation; preventing defeat or circumvention of the device by unauthorized persons; preventing operation of the vehicle by unauthorized entrants; and ensuring the reliability and durability of the device.

Pursuant to 49 U.S.C. 33106 and 49 CFR 543.7(b), the agency grants a petition for exemption from the parts-marking requirements of Part 541, either in whole or in part, if it determines that, based upon supporting evidence, the standard equipment antitheft device is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of Part 541. The agency finds that BMW has provided adequate reasons for its belief that the antitheft device for the MINI Countryman MPV line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard (49 CFR part 541).

This conclusion is based on the information BMW provided about its device.

For the foregoing reasons, the agency hereby grants in full BMW's petition for exemption for the MY 2017 MINI Countryman MPV line from the parts-marking requirements of 49 CFR part 541. The agency notes that 49 CFR part 541, Appendix A–1, identifies those lines that are exempted from the Theft Prevention Standard for a given MY. 49 CFR part 543.7(f) contains publication requirements incident to the disposition of all Part 543 petitions. Advanced listing, including the release of future product nameplates, the beginning model year for which the petition is granted and a general description of the antitheft device is necessary in order to notify law enforcement agencies of new vehicle lines exempted from the parts-marking requirements of the Theft Prevention Standard.

If BMW decides not to use the exemption for this line, it must formally notify the agency. If such a decision is made, the line must be fully marked as required by 49 CFR parts 541.5 and 541.6 (marking of major component parts and replacement parts).

NHTSA notes that if BMW wishes in the future to modify the device on which this exemption is based, the company may have to submit a petition to modify the exemption. Part 543.7(d) states that a Part 543 exemption applies only to vehicles that belong to a line exempted under this part and equipped with the antitheft device on which the line's exemption is based. Further, § 543.9(c)(2) provides for the submission of petitions "to modify an exemption to permit the use of an antitheft device similar to but differing from the one specified in that exemption."

The agency wishes to minimize the administrative burden that Part 543.9(c)(2) could place on exempted vehicle manufacturers and itself. The agency did not intend Part 543 to require the submission of a modification petition for every change to the components or design of an antitheft device. The significance of many such changes could be *de minimis*. Therefore, NHTSA suggests that if the manufacturer contemplates making any changes the effects of which might be characterized as *de minimis*, it should consult the agency before preparing and submitting a petition to modify.

Issued in Washington, DC, on April 18, 2016 under authority delegated in 49 CFR part 1.95

Raymond R. Posten,

Associate Administrator for Rulemaking.

[FR Doc. 2016–09767 Filed 4–26–16; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Comment Request; Interagency Guidance on Asset Securitization Activities

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995 (PRA).

In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The OCC is soliciting comment concerning renewal of its information collection titled, "Interagency Guidance on Asset Securitization Activities."

DATES: Comments must be submitted on or before June 27, 2016.

ADDRESSES: Because paper mail in the Washington, DC area and at the OCC is subject to delay, commenters are encouraged to submit comments by email, if possible. Comments may be sent to: Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557–0217, 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219. In addition, comments may be sent by fax to (571) 465–4326 or by electronic mail to *prainfo@occ.treas.gov.* You may personally inspect and photocopy comments at the OCC, 400 7th Street SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hard of hearing, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect and photocopy comments.

All comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, OCC Clearance Officer, (202) 649–5490 or, for persons who are deaf or hard of hearing, TTY, (202) 649–5597, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from OMB for each collection of information that they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, the OCC is publishing notice of the proposed collection of information set forth in this document.

Title: Interagency Guidance on Asset Securitization Activities.

OMB Control No.: 1557–0217.

Type of Review: Regular.

Description: This information collection applies to institutions engaged in asset securitization activities and provides that any institution engaged in these activities should maintain a written asset securitization policy, document the fair value of retained interests, and maintain a management information system to monitor asset securitization activities. Institution management uses the information collected to ensure the safe and sound operation of the institution's asset securitization activities. The OCC uses the information to evaluate the quality of an institution's risk management practices.

Affected Public: Businesses or other for-profit.

Burden Estimates:

Estimated Number of Respondents: 35 national banks and Federal savings associations.

Estimated Annual Burden: 1,827 hours.

Frequency of Response: On occasion.

Comments: The comments submitted in response to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the information collection burden;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: April 21, 2016.

Mary Hoyle Gottlieb,

Regulatory Specialist, Legislative and Regulatory Activities Division.

[FR Doc. 2016–09730 Filed 4–26–16; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

FEDERAL RESERVE SYSTEM

FEDERAL DEPOSIT INSURANCE CORPORATION

Proposed Agency Information Collection Activities; Comment Request; Correction

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury; Board of Governors of the Federal Reserve System (Board); and Federal Deposit Insurance Corporation (FDIC).

ACTION: Joint notice and request for comment; correction.

SUMMARY: The OCC, the Board, and the FDIC (the agencies) published a notice in the **Federal Register**, 81 FR 22702 (April 18, 2016), concerning Regulatory Capital Reporting for Institutions Subject to the Advanced Capital Adequacy Framework (FFIEC 101). This document corrects the date cited for the initial reporting of the Legal Entity Identifier by advanced approaches banking organizations from March 31, 2016, to September 30, 2016. This notice also extends the comment due date.

DATES: The comment period for the notice published April 18, 2016 (81 FR 22702) is extended. Comments must be submitted on or before June 27, 2016.

FOR FURTHER INFORMATION CONTACT: For further information about the proposed revisions to regulatory reporting requirements discussed in this notice, please contact any of the agency clearance officers whose names appear below. In addition, copies of the proposed revised FFIEC 101 form and instructions can be obtained at the FFIEC's Web site (*http://www.ffiec.gov/ffiec_report_forms.htm*).

OCC: Shaquita Merritt, OCC Clearance Officer, (202) 649–5490, or for persons who are deaf or hard of hearing, TTY, (202) 649–5597, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW., Washington, DC 20219.

Board: Nuha Elmaghrabi, Federal Reserve Board Clearance Officer, (202) 452–3829, Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551. Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

FDIC: Gary A. Kuiper, Counsel, (202) 898–3877, or Manuel E. Cabeza, Counsel, (202) 898–3767, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.

Correction

In the **Federal Register** of April 18, 2016, in FR Doc. 2016–08892, on page 22706, at the 29th line of the third column, remove "March 31, 2016" and add in its place "September 30, 2016".

Dated: April 20, 2016.

Stuart Feldstein,

Director, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency.

Board of Governors of the Federal Reserve System, April 20, 2016.

Robert deV. Frierson,

Secretary of the Board.

Dated at Washington, DC, this 19th day of April, 2016.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2016–09871 Filed 4–26–16; 8:45 am]

BILLING CODE 4810–33–6210–01–6714–01–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Submission for OMB Review; Leveraged Lending

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. chapter 35).

In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The OCC is soliciting comment concerning the renewal of its information collection titled, "Leveraged Lending." The OCC also is giving notice that it has sent the collection to OMB for review.

DATES: Comments must be received by May 27, 2016.

ADDRESSES: Because paper mail in the Washington, DC area and at the OCC is subject to delay, commenters are encouraged to submit comments by email, if possible. Comments may be sent to: Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557–0315, 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219. In addition, comments may be sent by fax to (571) 465–4326 or by electronic mail to *prainfo@occ.treas.gov*. You may personally inspect and photocopy comments at the OCC, 400 7th Street SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hard of hearing, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect and photocopy comments.

All comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Additionally, please send a copy of your comments by mail to: OCC Desk Officer, 1557–0315, U.S. Office of Management and Budget, 725 17th Street NW., #10235, Washington, DC 20503, or by email to: *oira submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, Clearance Officer, (202) 649–5490 or, for persons who are deaf or hard of hearing, TTY, (202) 649–5597, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW., Washington, DC 20219.

SUPPLEMENTARY INFORMATION: The OCC is proposing to extend OMB approval of the following information collection:

Title: Leveraged Lending.

OMB Control No.: 1557–0315.

Description: On March 22, 2013, the agencies[1] issued guidance stating that they expected financial institutions[2] to properly evaluate and monitor underwritten credit risks in leveraged loans, to understand the effect of changes in borrowers' business valuations on credit portfolio quality, and to assess the sensitivity of future credit losses to these changes in business valuations.[3] In underwriting such credits, financial institutions should ensure that borrowers are able to repay credits when due and that borrowers have sustainable capital structures, including bank borrowings and other debt, to support their continued operations through economic cycles. Financial institutions also should be able to demonstrate they understand the risks and the potential impact of stressful events and circumstances on borrowers' financial condition.

The final guidance stated that financial institutions should have: (i) Underwriting policies for leveraged lending, including stress-testing procedures for leveraged credits; (ii) risk management policies, including stress-testing procedures for pipeline exposures; and, (iii) policies and procedures for incorporating the results of leveraged credit and pipeline stress tests into the firm's overall stress-testing framework.

Respondents are financial institutions with leveraged lending activities as defined in the guidance.

Title: Leveraged Lending.

OMB Control No.: 1557–0315.

Frequency of Response: Annual.

Affected Public: Financial institutions with leveraged lending.

Burden Estimates:

Estimated number of respondents: 29.

Estimated total annual burden: 39,162 hours to build; 49,462 hours for ongoing use.

Total estimated annual burden: 88,624 hours.

Comments: On February 17, 2016, the OCC published a notice for 60 days of comment regarding the collection, 81 FR 8126. The OCC received one comment on the 60-day notice from an individual. The commenter questioned the utility and benefit of the information collection aspects of the guidance compared with the burden. Specifically, the commenter stated the information collections on stress-testing for leveraged lending, including for pipeline exposures, is already contained in other OCC or interagency guidance. The commenter also suggested that the OCC should define a leveraged loan and clarify the limits of acceptable leveraged lending risk.

The OCC believes that the information collections provide utility and benefit, as they can allow banks to monitor more closely their leveraged lending activity. Increased monitoring can improve a bank's response to potential deteriorations in the leveraged lending portfolio. Regarding burden, the leveraged lending information collections are voluntary. If a bank decides that the burdens of certain collections would outweigh the costs, then the bank can choose not to implement those collections. While the OCC has issued other guidance documents on stress-testing, either standalone or on an interagency basis, those documents provide higher-level guidance for stress-testing of all assets and liabilities. The leveraged lending guidance provides additional considerations for stress-testing specifically related to leveraged lending, which is not present in other OCC or interagency guidance.

During the initial issuance of the leveraged lending guidance, the OCC considered whether to establish a single definition of leveraged loan or leveraged lending. However, the agencies concluded that leveraged lending is not homogenous across industries or banks, and did not believe that a "one-size-fits-all" definition was appropriate. The OCC continues to believe that those banks following the leveraged lending guidance should have this flexibility in setting the parameters of their leveraged lending and risk management programs.

Comments continue to be requested on:

(a) Whether the information collections are necessary for the proper performance of the OCC's functions, including whether the information has practical utility;

(b) The accuracy of the OCC's estimates of the burden of the information collections, including the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of information collections on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: April 21, 2016.

Mary Hoyle Gottlieb,

Regulatory Specialist, Office of the Comptroller of the Currency.

[FR Doc. 2016–09878 Filed 4–26–16; 8:45 am]

BILLING CODE 4810–33–P

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[1] OCC, Board of Governors of the Federal Reserve System, and Federal Deposit Insurance Corporation.

[2] For the OCC, the term "financial institution" or "institution" includes national banks, Federal savings associations, and Federal branches and agencies supervised by the OCC.

[3] 78 FR 17766 (March 22, 2013).

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting; correction.

SUMMARY: In the **Federal Register** notice that was originally published on April 14, 2016, (Volume 81, Number 72, Page 22166) the time was written as 3:00 p.m. EST instead of 2:00 p.m. EST. The meeting time is: 2:00 p.m. EST, Thursday, May 19, 2016.

DATES: The meeting will be held Thursday, May 19, 2016.

FOR FURTHER INFORMATION CONTACT: Antoinette Ross at 1–888–912–1227 or (202) 317–4110.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee will be held Thursday, May 19, 2016, at 2:00 p.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. Due to limited conference lines, notification of intent to participate must be made with Antoinette Ross. For more information please contact: Antoinette Ross at 1–888–912–1227 or (202) 317–4110, or write TAP Office, 1111 Constitution Avenue NW., Room 1509—National Office, Washington, DC 20224, or contact us at the Web site: *http://www.improveirs.org.*

The committee will be discussing various issues related to Taxpayer Communications and public input is welcome.

Dated: April 21, 2016.

Antoinette Ross,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2016–09764 Filed 4–26–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Joint Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel Joint Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Wednesday, May 25, 2016.

FOR FURTHER INFORMATION CONTACT: Kim Vinci at 1–888–912–1227 or 916–974–5086.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Joint Committee will be held Wednesday, May 25, 2016, at 1:00 p.m. Eastern Time via teleconference. The public is invited to make oral comments or submit written statements for consideration. For more information please contact: Kim Vinci at 1–888–912–1227 or 916–974–5086, TAP Office, 4330 Watt Ave., Sacramento, CA 95821, or contact us at the Web site: *http://www.improveirs.org.*

The agenda will include various committee issues for submission to the IRS and other TAP related topics. Public input is welcomed.

Dated: April 21, 2016.

Antoinette Ross,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2016–09763 Filed 4–26–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Multiemployer Pension Plan Application To Reduce Benefits

AGENCY: Department of the Treasury.

ACTION: Notice of availability; request for comments.

SUMMARY: The Board of Trustees of the Iron Workers Local Union 16 Pension Fund, a multiemployer pension plan, has submitted an application to Treasury to reduce benefits under the plan in accordance with the Multiemployer Pension Reform Act of 2014 (MPRA). The purpose of this notice is to announce that the application submitted by the Board of Trustees of the Iron Workers Local Union 16 Pension Fund has been published on the Web site of the Department of the Treasury (Treasury), and to request public comments on the application from interested parties, including contributing employers, employee organizations, and participants and beneficiaries of the Iron Workers Local Union 16 Pension Fund.

DATES: Comments must be received by June 9, 2016.

ADDRESSES: You may submit comments electronically through the Federal eRulemaking Portal at *http://www.regulations.gov,* in accordance with the instructions on that site. Electronic submissions through *www.regulations.gov* are encouraged.

Comments may also be mailed to the Department of the Treasury, MPRA Office, 1500 Pennsylvania Avenue, NW., Room 1224, Washington, DC 20220. Attn: Deva Kyle. Comments sent via facsimile and email will not be accepted.

Additional Instructions. All comments received, including attachments and other supporting materials, will be made available to the public. Do not include any personally identifiable information (such as Social Security number, name, address, or other contact information) or any other information in your comment or supporting materials that you do not want publicly disclosed. Treasury will make comments available for public inspection and copying on *www.regulations.gov* or upon request. Comments posted on the Internet can be retrieved by most Internet search engines.

FOR FURTHER INFORMATION CONTACT: For information regarding the application from the Board of Trustees of the Iron Workers Local Union 16 Pension Fund, please contact Treasury at (202) 622–1534 (not a toll-free number).

SUPPLEMENTARY INFORMATION: The Multiemployer Pension Reform Act of 2014 (MPRA) amended the Internal Revenue Code to permit a multiemployer plan that is projected to have insufficient funds to reduce pension benefits payable to participants and beneficiaries if certain conditions are satisfied. In order to reduce benefits, the plan sponsor is required to submit an application to the Secretary of the Treasury, which Treasury, in consultation with the Pension Benefit Guaranty Corporation (PBGC) and the Department of Labor, is required to approve or deny.

On March 26, 2016, the Board of Trustees of the Iron Workers Local Union 16 Pension Fund submitted an application for approval to reduce benefits under the plan. As required by MPRA, that application has been published on Treasury's Web site at *https://auth.treasury.gov/services/Pages/Plan-Applications.aspx.* Treasury is publishing this notice in the **Federal Register**, in consultation with PBGC and the Department of Labor, to solicit public comments on all aspects of the Iron Workers Local Union 16 Pension Fund application.

Comments are requested from interested parties, including contributing employers, employee organizations, and participants and beneficiaries of the Iron Workers Local Union 16 Pension Fund. Consideration will be given to any comments that are timely received by Treasury.

Dated: April 20, 2016.

David R. Pearl,

Executive Secretary, Department of the Treasury.

[FR Doc. 2016–09836 Filed 4–26–16; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

April 22, 2016.

The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before May 27, 2016 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimates, or any other aspect of the information collections, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8117, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained by emailing *PRA@treasury.gov,* calling (202) 622–1295, or viewing the entire information collection request at *www.reginfo.gov.*

Internal Revenue Service (IRS)

OMB Control Number: 1545–0054.

Type of Review: Extension without change of a currently approved collection.

Title: Ownership Certificate.

Form: 1000.

Abstract: Form 1000, Ownership Certificate, is filed with a withholding agent for interest payments on bonds that have a tax-free covenant and that were issued before 1934 by a domestic corporation or a resident or nonresident foreign corporation.

Affected Public: Businesses or other for-profits.

Estimated Annual Burden Hours: 5,040.

OMB Control Number: 1545–0169.

Type of Review: Reinstatement without change of a previously approved collection.

Title: Form 4461: Application for Approval of Master or Prototype Defined Contribution Plan; Form 4461–A: Application for Approval of Master or Prototype Defined Benefit Plan; Form 4461–B: Application for Approval of Master or Prototype or Volume Submitter Plans.

Form: Forms 4461, 4461–A, 4461–B.

Abstract: Form 4461 is used to apply for approval of Master or Prototype (M&P) or Volume Submitter (VS) defined contribution plans. Form 4461–A is used to apply for approval of a M&P or VS defined benefit plan, and Attachment 1–A is submitted with the application. Form 4461–B is used to apply for approval of a plan submitted by a mass submitter on behalf of an adopting sponsor or practitioner, which is based on a plan submitted by the mass submitter.

Affected Public: Businesses or other for-profits.

Estimated Total Annual Burden Hours: 65,765.

OMB Control Number: 1545–1673.

Type of Review: Reinstatement with change of a previously approved collection.

Title: Employee Plans Compliance Resolution System (EPCRS).

Form: Form 14568, Forms 14568–A thru –I, Form 8950, Form 8951.

Abstract: The information requested in Revenue Procedure 2015–27 is required to enable the Internal Revenue Service to make determinations on the issuance of various types of closing agreements and compliance statements. The issuance of the agreements and statements allow individual plans to maintain their tax-qualified status. Applicants under the Voluntary Correction Program (VCP) must file Forms 8950 and 8951, and the appropriate schedule(s) to the applicable part of the model compliance statement, in order to request written approval from the IRS for a correction of a qualified plan that has failed to comply with the requirements of the Internal Revenue Code. Rev. Proc. 2015–28 contains modifications to Rev. Proc. 2013–12, reflecting new safe harbor EPCRS correction methods.

Affected Public: Businesses or other for-profits.

Estimated Annual Burden Hours: 190,941.

OMB Control Number: 1545–1842.

Type of Review: Extension without change of a currently approved collection.

Title: Health Coverage Tax Credit Registration Form.

Form: 13441, 13441–EZ.

Abstract: If eligible, section 35 of the Internal Revenue Code allows a credit for payments made to buy certain types of health coverage during the tax year. Information submitted on Form 13441, Health Coverage Tax Credit Registration Form, is used to determine if a taxpayer qualifies for the advance payment of the Health Coverage Tax Credit (HCTC). Form 13441–EZ is used during an HCTC Program-sponsored group registration for the monthly HCTC Program.

Affected Public: Individuals or Households.

Estimated Annual Burden Hours: 1,800.

OMB Control Number: 1545–1899.

Type of Review: Revision of a currently approved collection.

Title: Timely Mailing Treated As Timely Filing.

Abstract: The revenue procedure provides the criteria that will be used to determine whether a private delivery service ("PDS") qualifies as a designated private delivery service ("designated PDS") and also provides the procedures under which a PDS can apply to become a designated PDS. The regulations provide guidance as to the only ways to establish prima facie evidence of delivery of documents that have a filing deadline prescribed by the internal revenue laws, absent direct proof of actual delivery.

Affected Public: Individuals or Households, Businesses or other for-profits.

Estimated Annual Burden Hours: 1,087,834.

OMB Control Number: 1545–2004.

Type of Review: Extension without change of a currently approved collection.

Title: Deduction for Energy Efficient Commercial Buildings.

Abstract: Notice 2006–52 provides a process that allows a taxpayer who owns a commercial building and installs property as part of the commercial building's interior lighting systems, heating, cooling, ventilation, and hot water systems, or building envelope to obtain a certification that the property satisfies the energy efficiency requirements of § 179D(c)(1) and (d) of the Internal Revenue Code. Notice 2008–40 clarifies and amplifies 2006–52.

Affected Public: Businesses or other for-profits.

Estimated Annual Burden Hours: 3,761.

OMB Control Number: 1545–2014.

Type of Review: Extension without change of a currently approved collection.

Title: TD 9452, Application of Separate Limitations to Dividends from Noncontrolled Section 902 Corporations.

Abstract: Final regulations under section 904 of the Internal Revenue Code provide guidance relating to the application of section 904 to dividends paid by a foreign corporation that is a noncontrolled section 902 corporation as defined in section 904(d)(2)(E).

Affected Public: Businesses or other for-profits.

Estimated Annual Burden Hours: 25.

Brenda Simms,

Treasury PRA Clearance Officer.

[FR Doc. 2016–09855 Filed 4–26–16; 8:45 am]

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 412, 413, et al.

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2017 Rates; Quality Reporting Requirements for Specific Providers; Graduate Medical Education; Hospital Notification Procedures Applicable to Beneficiaries Receiving Observation Services; and Technical Changes Relating to Costs to Organizations and Medicare Cost Reports; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 412, 413, and 485

[CMS–1655–P]

RIN 0938–AS77

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2017 Rates; Quality Reporting Requirements for Specific Providers; Graduate Medical Education; Hospital Notification Procedures Applicable to Beneficiaries Receiving Observation Services; and Technical Changes Relating to Costs to Organizations and Medicare Cost Reports

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: We are proposing to revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from our continuing experience with these systems for FY 2017. Some of the proposed changes would implement certain statutory provisions contained in the Pathway for Sustainable Growth (SGR) Reform Act of 2013, the Improving Medicare Post-Acute Care Transformation Act of 2014, the Notice of Observation Treatment and Implications for Care Eligibility Act of 2015, and other legislation. We also are providing the estimated market basket update to apply to the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis subject to these limits for FY 2017.

We are proposing to update the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) for FY 2017.

In addition, we are proposing to make changes relating to direct graduate medical education (GME) and indirect medical education (IME) payments to hospitals with rural track training programs. We are proposing to establish new requirements or revise requirements for quality reporting by specific providers (acute care hospitals, PPS-exempt cancer hospitals, LTCHs, and inpatient psychiatric facilities) that are participating in Medicare, including related provisions for eligible hospitals and critical care hospitals (CAHs) participating in the Electronic Health Record (EHR) Incentive Program. We are proposing to update policies relating to the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition (HAC) Reduction Program. We also are proposing to: Implement statutory provisions that require hospitals and CAHs to furnish notification to Medicare beneficiaries, including Medicare Advantage enrollees, when the beneficiaries receive outpatient observation services for more than 24 hours; announce the implementation of the Frontier Community Health Integration Project Demonstration; and make technical corrections and changes to regulations relating to costs to organizations and Medicare cost reports.

DATES: To be assured consideration, comments must be received at one of the addresses provided in the **ADDRESSES** section, no later than 5 p.m. EDT on June 17, 2016.

ADDRESSES: In commenting, please refer to file code CMS–1655–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may (and we encourage you to) submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the "submit a comment" tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1655–P, P.O. Box 8011, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments via express or overnight mail to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1655–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call the telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Ing Jye Cheng, (410) 786–4548, and Donald Thompson, (410) 786–4487, Operating Prospective Payment, MS–DRGs, Wage Index, New Medical Service and Technology Add-On Payments, Hospital Geographic Reclassifications, Graduate Medical Education, Capital Prospective Payment, Excluded Hospitals, Medicare Disproportionate Share Hospital (DSH) Issues, Medicare-Dependent Small Rural Hospital (MDH) Program, and Low-Volume Hospital Payment Adjustment Issues.

Michele Hudson, (410) 786–4487, and Emily Lipkin, (410) 786–3633, Long-Term Care Hospital Prospective Payment System and MS–LTC–DRG Relative Weights Issues.

Mollie Knight (410) 786–7948, and Bridget Dickensheets, (410) 786–8670, Rebasing and Revising the LTCH Market Basket Issues.

Siddhartha Mazumdar, (410) 786–6673, Rural Community Hospital Demonstration Program Issues.

Jason Pteroski, (410) 786–4681, and Siddhartha Mazumdar, (410) 786–6673, Frontier Community Health Integration Project Demonstration Issues.

Kathryn McCann Smith, (410) 786–7623, Hospital Notification Procedures for Beneficiaries Receiving Outpatient Observation Services Issues; or

Stephanie Simons, (206) 615–2420, only for Related Medicare Health Plans Issues.

Lein Han, (617) 879–0129, Hospital Readmissions Reduction Program—Readmission Measures for Hospitals Issues.

Delia Houseal, (410) 786–2724, Hospital-Acquired Condition Reduction Program and Hospital Readmissions Reduction Program—Program Administration Issues.

Joseph Clift, (410) 786–4165, Hospital-Acquired Condition Reduction Program—Measures Issues.

James Poyer, (410) 786–2261, Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing—Program Administration, Validation, and Reconsideration Issues.

Cindy Tourison, (410) 786–1093, Hospital Inpatient Quality Reporting—Measures Issues Except Hospital Consumer Assessment of Healthcare Providers and Systems Issues; and Readmission Measures for Hospitals Issues.

Kim Spaulding Bush, (410) 786–3232, Hospital Value-Based Purchasing Efficiency Measures Issues.

Elizabeth Goldstein, (410) 786–6665, Hospital Inpatient Quality Reporting—Hospital Consumer Assessment of Healthcare Providers and Systems Measures Issues.

James Poyer, (410) 786–2261, PPS-Exempt Cancer Hospital Quality Reporting Issues.

Mary Pratt, (410) 786–6867, Long-Term Care Hospital Quality Data Reporting Issues.

Jeffrey Buck, (410) 786–0407 and Cindy Tourison (410) 786–1093, Inpatient Psychiatric Facilities Quality Data Reporting Issues.

Deborah Krauss, (410) 786–5264, and Lisa Marie Gomez, (410) 786–1175, EHR Incentive Program Clinical Quality Measure Related Issues.

Elizabeth Myers, (410) 786–4751, EHR Incentive Program Nonclinical Quality Measure Related Issues.

Lauren Wu, (202) 690–7151, Certified EHR Technology Related Issues.

Kellie Shannon, (410) 786–0416, Technical Changes Relating to Costs to Organizations and Medicare Cost Reports Issues.

SUPPLEMENTARY INFORMATION:

Electronic Access

Inspection of Public Comments: All public comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all public comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through Federal Digital System (FDsys), a service of the U.S. Government Printing Office. This database can be accessed via the Internet at: *http://www.gpo.gov/fdsys.*

Tables Available Only Through the Internet on the CMS Web Site

In the past, a majority of the tables referred to throughout this preamble and in the Addendum to the proposed rule and the final rule were published in the **Federal Register** as part of the annual proposed and final rules. However, beginning in FY 2012, some of the IPPS tables and LTCH PPS tables are no longer published in the **Federal Register**. Instead, these tables generally will be available only through the Internet. The IPPS tables for this proposed rule are available through the Internet on the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* Click on the link on the left side of the screen titled, "FY 2017 IPPS Proposed Rule Home Page" or "Acute Inpatient—Files for Download". The LTCHy PPS tables for this FY 2017 proposed rule are available through the Internyet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1655–P. For further details on the contents of the tables referenced in this proposed rule, we refer readers to section VI. of the Addendum to this proposed rule.

Readers who experience any problems accessing any of the tables that are posted on the CMS Web sites identified above should contact Michael Treitel at (410) 786–4552.

Acronyms

3M	3M Health Information System
AAMC	Association of American Medical Colleges
ACGME	Accreditation Council for Graduate Medical Education
ACoS	American College of Surgeons
AHA	American Hospital Association
AHIC	American Health Information Community
AHIMA	American Health Information Management Association
AHRQ	Agency for Healthcare Research and Quality
AJCC	American Joint Committee on Cancer
ALOS	Average length of stay-
ALTHA	Acute Long-Term Hospital Association
AMA	American Medical Association
AMGA	American Medical Group Association
AMI	Acute myocardial infarction
AOA	American Osteopathic Association
APR DRG	All Patient Refined Diagnosis Related Group System
APRN	Advanced practice registered nurse
ARRA	American Recovery and Reinvestment Act of 2009, Public Law 111–5
ASCA	Administrative Simplification Compliance Act of 2002, Public Law 107–105
ASITN	American Society of Interventional and Therapeutic Neuroradiology
ASPE	Assistant Secretary for Planning and Evaluation (DHHS)
ATRA	American Taxpayer Relief Act of 2012, Public Law 112–240
BBA	Balanced Budget Act of 1997, Public Law 105–33
BBRA	Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999, Public Law 106–113
BIPA	Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Benefits Improvement and Protection Act of 2000, Public Law 106–554
BLS	Bureau of Labor Statistics
CABG	Coronary artery bypass graft [surgery]
CAH	Critical access hospital
CARE	[Medicare] Continuity Assessment Record & Evaluation [Instrument]
CART	CMS Abstraction & Reporting Tool
CAUTI	Catheter-associated urinary tract infection
CBSAs	Core-based statistical areas
CC	Complication or comorbidity
CCN	CMS Certification Number
CCR	Cost-to-charge ratio
CDAC	[Medicare] Clinical Data Abstraction Center
CDAD	*Clostridium difficile*-associated disease
CDC	Centers for Disease Control and Prevention
CERT	Comprehensive error rate testing
CDI	*Clostridium difficile* [C. difficile] infection
CFR	Code of Federal Regulations
CLABSI	Central line-associated bloodstream infection
CIPI	Capital input price index
CMI	Case-mix index
CMS	Centers for Medicare & Medicaid Services
CMSA	Consolidated Metropolitan Statistical Area
COBRA	Consolidated Omnibus Reconciliation Act of 1985, Public Law 99–272
COLA	Cost-of-living adjustment
CoP	[Hospital] condition of participation
COPD	Chronic obstructive pulmonary disease
CPI	Consumer price index
CQL	Clinical quality language
CQM	Clinical quality measure
CY	Calendar year
DACA	Data Accuracy and Completeness Acknowledgement

DPP Disproportionate patient percentage
DRA Deficit Reduction Act of 2005, Public Law 109–171
DRG Diagnosis-related group
DSH Disproportionate share hospital
EBRT External beam radiotherapy
ECE Extraordinary circumstances exemption
ECI Employment cost index
eCQM Electronic clinical quality measure
EDB [Medicare] Enrollment Database
EHR Electronic health record
EMR Electronic medical record
EMTALA Emergency Medical Treatment and Labor Act of 1986, Public Law 99–272
EP Eligible professional
FAH Federation of American Hospitals
FDA Food and Drug Administration
FFY Federal fiscal year
FPL Federal poverty line
FQHC Federally qualified health center
FR Federal Register
FTE Full-time equivalent
FY Fiscal year
GAF Geographic Adjustment Factor
GME Graduate medical education
HAC Hospital-acquired condition
HAI Healthcare-associated infection
HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems
HCFA Health Care Financing Administration
HCO High-cost outlier
HCP Healthcare personnel
HCRIS Hospital Cost Report Information System
HF Heart failure
HHA Home health agency
HHS Department of Health and Human Services
HICAN Health Insurance Claims Account Number
HIPAA Health Insurance Portability and Accountability Act of 1996, Public Law 104–191
HIPC Health Information Policy Council
HIS Health information system
HIT Health information technology
HMO Health maintenance organization
HPMP Hospital Payment Monitoring Program
HSA Health savings account
HSCRC [Maryland] Health Services Cost Review Commission
HSRV Hospital-specific relative value
HSRVcc Hospital-specific relative value cost center
HQA Hospital Quality Alliance
HQI Hospital Quality Initiative
HwH Hospital-within-hospital
ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification
ICD–10–CM International Classification of Diseases, Tenth Revision, Clinical Modification
ICD–10–PCS International Classification of Diseases, Tenth Revision, Procedure Coding System
ICR Information collection requirement
ICU Intensive care unit
IGI IHS Global Insight, Inc.
IHS Indian Health Service
IME Indirect medical education
IMPACT Act Improving Medicare Post-Acute Care Transformation Act of 2014, Public Law 113–185
I–O Input-Output
IOM Institute of Medicine
IPF Inpatient psychiatric facility
IPFQR Inpatient Psychiatric Facility Quality Reporting [Program]
IPPS [Acute care hospital] inpatient prospective payment system
IRF Inpatient rehabilitation facility
IQR [Hospital] Inpatient Quality Reporting
LAMCs Large area metropolitan counties
LEP Limited English proficiency
LOC Limitation on charges
LOS Length of stay
LTC–DRG Long-term care diagnosis-related group
LTCH Long-term care hospital
LTCH QRP Long-Term Care Hospital Quality Reporting Program
MA Medicare Advantage
MAC Medicare Administrative Contractor
MACRA Medicare Access and CHIP Reauthorization Act of 2015, Public Law 114–10
MAP Measure Application Partnership
MCC Major complication or comorbidity
MCE Medicare Code Editor
MCO Managed care organization
MDC Major diagnostic category
MDH Medicare-dependent, small rural hospital
MedPAC Medicare Payment Advisory Commission
MedPAR Medicare Provider Analysis and Review File
MEI Medicare Economic Index
MGCRB Medicare Geographic Classification Review Board
MIEA–TRHCA Medicare Improvements and Extension Act, Division B of the Tax Relief and Health Care Act of 2006, Public Law 109–432
MIPPA Medicare Improvements for Patients and Providers Act of 2008, Public Law 110–275
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173
MMEA Medicare and Medicaid Extenders Act of 2010, Public Law 111–309
MMSEA Medicare, Medicaid, and SCHIP Extension Act of 2007, Public Law 110–173
MOON Medicare Outpatient Observation Notice
MRHFP Medicare Rural Hospital Flexibility Program
MRSA Methicillin-resistant *Staphylococcus aureus*
MSA Metropolitan Statistical Area
MS–DRG Medicare severity diagnosis-related group
MS–LTC–DRG Medicare severity long-term care diagnosis-related group
MU Meaningful Use [EHR Incentive Program]
MUC Measure under consideration
NAICS North American Industrial Classification System
NALTH National Association of Long Term Hospitals
NCD National coverage determination
NCHS National Center for Health Statistics
NCQA National Committee for Quality Assurance
NCVHS National Committee on Vital and Health Statistics
NECMA New England County Metropolitan Areas
NHSN National Healthcare Safety Network
NOP Notice of Participation
NOTICE Act Notice of Observation Treatment and Implication for Care Eligibility Act, Public Law 114–42
NQF National Quality Forum
NQS National Quality Strategy
NTIS National Technical Information Service
NTTAA National Technology Transfer and Advancement Act of 1991, Public Law 104–113
NUBC National Uniform Billing Code
NVHRI National Voluntary Hospital Reporting Initiative
OACT [CMS'] Office of the Actuary
OBRA 86 Omnibus Budget Reconciliation Act of 1986, Public Law 99–509
OES Occupational employment statistics
OIG Office of the Inspector General
OMB [Executive] Office of Management and Budget
ONC Office of the National Coordinator for Health Information Technology
OPM [U.S.] Office of Personnel Management
OQR [Hospital] Outpatient Quality Reporting
O.R. Operating room
OSCAR Online Survey Certification and Reporting [System]
PAC Post-acute care
PAMA Protecting Access to Medicare Act of 2014, Public Law 113–93
PCH PPS-exempt cancer hospital
PCHQR PPS-exempt cancer hospital quality reporting
PMSAs Primary metropolitan statistical areas
POA Present on admission
PPI Producer price index
PPR Potentially Preventable Readmissions
PPS Prospective payment system
PRM Provider Reimbursement Manual
ProPAC Prospective Payment Assessment Commission
PRRB Provider Reimbursement Review Board
PRTFs Psychiatric residential treatment facilities
PSF Provider-Specific File
PSI Patient safety indicator
PS&R Provider Statistical and Reimbursement [System]
PQRS Physician Quality Reporting System
PUF Public use file
QDM Quality data model
QIES ASAP Quality Improvement Evaluation System Assessment Submission and Processing
QIG Quality Improvement Group [CMS]
QIO Quality Improvement Organization
QM Quality measure
QRDA Quality Reporting Document Architecture
RFA Regulatory Flexibility Act, Public Law 96–354
RHC Rural health clinic
RHQDAPU Reporting hospital quality data for annual payment update
RIM Reference information model
RNHCI Religious nonmedical health care institution
RPL Rehabilitation psychiatric long-term care (hospital)
RRC Rural referral center

RSMR Risk-standard mortality rate
RSP Risk-standardized payment
RSSR Risk-standard readmission rate
RTI Research Triangle Institute, International
RUCAs Rural-urban commuting area codes
RY Rate year
SAF Standard Analytic File
SCH Sole community hospital
SCHIP State Child Health Insurance Program
SCIP Surgical Care Improvement Project
SFY State fiscal year
SGR Sustainable Growth Rate
SIC Standard Industrial Classification
SIR Standardized infection ratio
SNF Skilled nursing facility
SNF QRP Skilled Nursing Facility Quality Reporting Program
SNF VBP Skilled Nursing Facility Value-Based Purchasing
SOCs Standard occupational classifications
SOM State Operations Manual
SRR Standardized risk ratio
SSI Surgical site infection
SSI Supplemental Security Income
SSO Short-stay outlier
SUD Substance use disorder
TEFRA Tax Equity and Fiscal Responsibility Act of 1982, Public Law 97–248
TEP Technical expert panel
THA/TKA Total hip arthroplasty/total knee arthroplasty
TMA TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007, Public Law 110–90
TPS Total Performance Score
UHDDS Uniform hospital discharge data set
UR Utilization review
VBP [Hospital] Value Based Purchasing [Program]
VTE Venous thromboembolism

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I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

This proposed rule would make payment and policy changes under the Medicare inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals as well as for certain hospitals and hospital units excluded from the IPPS. In addition, it would make payment and policy changes for inpatient hospital services provided by long-term care hospitals (LTCHs) under the long-term care hospital prospective payment system (LTCH PPS). It also would make policy changes to programs associated with Medicare IPPS hospitals, IPPS-excluded hospitals, and LTCHs.

We are proposing to establish new requirements or revise requirements for quality reporting by specific providers (acute care hospitals, PPS-exempt cancer hospitals, LTCHs, and inpatient psychiatric facilities) that are participating in Medicare, including related provisions for eligible hospitals and critical assess hospitals (CAHs) participating in the Electronic Health Record (EHR) Incentive Program. We are proposing to update policies relating to the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition (HAC) Reduction Program. We also are proposing to: Implement statutory provisions that require hospitals and CAHs to furnish notification to Medicare beneficiaries, including Medicare Advantage enrollees, when the beneficiaries receive outpatient observation services for more than 24 hours; announce the implementation of the Frontier Community Health Integration Project Demonstration; make technical corrections and changes to regulations relating to costs to organizations and Medicare cost reports.

Under various statutory authorities, we are proposing to make changes to the Medicare IPPS, to the LTCH PPS, and to other related payment methodologies and programs for FY 2017 and subsequent fiscal years. These statutory authorities include, but are not limited to, the following:

- Section 1886(d) of the Social Security Act (the Act), which sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires that, instead of paying for capital-related costs of inpatient hospital services on a reasonable cost basis, the Secretary use a prospective payment system (PPS).
- Section 1886(d)(1)(B) of the Act, which specifies that certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Rehabilitation hospitals and units; LTCHs; psychiatric hospitals and units; children's hospitals; and cancer hospitals. Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS.
- Sections 123(a) and (c) of Public Law 106–113 and section 307(b)(1) of Public Law 106–554 (as codified under section 1886(m)(1) of the Act), which provide for the development and implementation of a prospective payment system for payment for inpatient hospital services of long-term care hospitals (LTCHs) described in section 1886(d)(1)(B)(iv) of the Act.
- Sections 1814(l), 1820, and 1834(g) of the Act, which specify that payments are made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services and that these payments are generally based on 101 percent of reasonable cost.
- Section 1866(k) of the Act, as added by section 3005 of the Affordable Care Act, which establishes a quality reporting program for hospitals described in section 1886(d)(1)(B)(v) of the Act, referred to as "PPS-exempt cancer hospitals."
- Section 1886(a)(4) of the Act, which specifies that costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act.
- Section 1886(b)(3)(B)(viii) of the Act, which requires the Secretary to reduce the applicable percentage increase in payments to a subsection (d) hospital for a fiscal year if the hospital does not submit data on measures in a form and manner, and at a time, specified by the Secretary.
- Section 1886(o) of the Act, which requires the Secretary to establish a Hospital Value-Based Purchasing (VBP) Program under which value-based incentive payments are made in a fiscal year to hospitals meeting performance standards established for a performance period for such fiscal year.
- Section 1886(p) of the Act, as added by section 3008 of the Affordable Care Act, which establishes a Hospital-Acquired Condition (HAC) Reduction Program, under which payments to applicable hospitals are adjusted to provide an incentive to reduce hospital-acquired conditions.
- Section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act and amended by section 10309 of the Affordable Care Act, which establishes the "Hospital Readmissions Reduction Program" effective for discharges from an "applicable hospital" beginning on or after October 1, 2012, under which payments to those hospitals under section 1886(d) of the Act will be reduced to account for certain excess readmissions.
- Section 1886(r) of the Act, as added by section 3133 of the Affordable Care Act, which provides for a reduction to disproportionate share hospital (DSH) payments under section 1886(d)(5)(F) of the Act and for a new uncompensated care payment to eligible hospitals. Specifically, section 1886(r) of the Act requires that, for fiscal year 2014 and each subsequent fiscal year, subsection (d) hospitals that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act will receive two separate payments: (1) 25 percent of the amount they previously would have received under section 1886(d)(5)(F) of the Act for DSH ("the empirically justified amount"), and (2) an additional payment for the DSH hospital's proportion of uncompensated care, determined as the product of three factors. These three factors are: (1) 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act; (2) 1 minus the percent change in the percent of individuals under the age of 65 who are uninsured (minus 0.1 percentage points for FY 2014, and minus 0.2 percentage points for FY 2015 through FY 2017); and (3) a hospital's uncompensated care amount relative to the uncompensated care amount of all DSH hospitals expressed as a percentage.
- Section 1886(m)(6) of the Act, as added by section 1206(a)(1) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67), which provided for the establishment of site neutral payment rate criteria under the LTCH PPS with implementation beginning in FY 2016.
- Section 1886(m)(5)(D)(iv) of the Act, as added by section 1206 (c) of the Pathway for SGR Reform Act of 2013, which provides for the establishment of a functional status quality measure under the LTCH QRP for change in

mobility among inpatients requiring ventilator support.

- Section 1899B of the Act, as added by the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act), which imposes data reporting requirements for certain post-acute care providers, including LTCHs.
- Section 1886(d)(12) of the Act, as amended by section 204 of the Medicare Access and CHIP Reauthorization Act of 2015, which extended, through FY 2017, changes to the inpatient hospital payment adjustment for certain low-volume hospitals; and section 1886(d)(5)(G) of the Act, as amended by section 205 of the Medicare Access and CHIP Reauthorization Act of 2015, which extended, through FY 2017, the Medicare-dependent, small rural hospital (MDH) program.

2. Summary of the Major Provisions

a. MS–DRG Documentation and Coding Adjustment

Section 631 of the American Taxpayer Relief Act (ATRA, Pub. L. 112–240) amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment to the standardized amount of Medicare payments to acute care hospitals to account for changes in MS–DRG documentation and coding that do not reflect real changes in case-mix, totaling $11 billion over a 4-year period of FYs 2014, 2015, 2016, and 2017. This adjustment represents the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013. Prior to the ATRA, this amount could not have been recovered under Public Law 110–90.

While our actuaries estimated that a −9.3 percent adjustment to the standardized amount would be necessary if CMS were to fully recover the $11 billion recoupment required by section 631 of the ATRA in one year, it is often our practice to delay or phase in rate adjustments over more than one year, in order to moderate the effects on rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, we made a −0.8 percent recoupment adjustment to the standardized amount in FY 2014, FY 2015, and FY 2016. For FY 2017, we are proposing to make an additional −1.5 percent recoupment adjustment to the standardized amount.

b. Adjustment to IPPS Rates Resulting From 2-Midnight Policy

In this proposed rule, we are proposing a permanent adjustment of (1/0.998) to the standardized amount, the hospital-specific payment rates, and the national capital Federal rate using our authority under sections 1886(d)(5)(I)(i) and 1886(g) of the Act to prospectively remove the 0.2 percent reduction to the rate put in place in FY 2014 to offset the estimated increase in IPPS expenditures as a result of the 2-midnight policy. In addition, we are proposing a temporary one-time prospective increase to the FY 2017 standardized amount, the hospital-specific payment rates, and the national capital Federal rate of 0.6 percent by including a temporary one-time factor of 1.006 in the calculation of the standardized amount, the hospital-specific payment rates, and the national capital Federal rate using our authority under sections 1886(d)(5)(I)(i) and 1886(g) of the Act, to address the effects of the 0.2 percent reduction to the rate for the 2-midnight policy in effect for FYs 2014, 2015, and 2016.

c. Reduction of Hospital Payments for Excess Readmissions

We are proposing to make changes to policies for the Hospital Readmissions Reduction Program, which is established under section 1886(q) of the Act, as added by section 3025 of the Affordable Care Act, as amended by section 10309 of the Affordable Care Act. The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions. For FY 2017 and subsequent years, the reduction is based on a hospital's risk-adjusted readmission rate during a 3-year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG). In this proposed rule, to align with other quality reporting programs and allow us to post data as soon as possible, we are clarifying our public reporting policy so that excess readmission rates will be posted to the *Hospital Compare* Web site as soon as feasible following the preview period, and we are proposing the methodology to include the addition of the CABG applicable condition in the calculation of the readmissions payment adjustment for FY 2017.

d. Hospital Value-Based Purchasing (VBP) Program

Section 1886(o) of the Act requires the Secretary to establish a Hospital VBP Program under which value-based incentive payments are made in a fiscal year to hospitals based on their performance on measures established for a performance period for such fiscal year.

In this proposed rule, we are proposing to refine two previously adopted measures beginning with the FY 2019 program year, to update one previously adopted measure beginning with the FY 2021 program year, to adopt two new measures beginning with the FY 2021 program year, and to adopt one new measure beginning with the FY 2022 program year. We also are proposing to change the performance period for one previously adopted measure for the FY 2018 program year and to change the name of the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain to the Person and Community Engagement domain beginning with the FY 2019 program year. In addition, we are proposing changes to the immediate jeopardy citation policy.

e. Hospital-Acquired Condition (HAC) Reduction Program

Section 1886(p) of the Act, as added under section 3008(a) of the Affordable Care Act, establishes an incentive to hospitals to reduce the incidence of hospital-acquired conditions by requiring the Secretary to make an adjustment to payments to applicable hospitals effective for discharges beginning on October 1, 2014. This 1-percent payment reduction applies to a hospital whose ranking is in the top quartile (25 percent) of all applicable hospitals, relative to the national average, of conditions acquired during the applicable period and on all of the hospital's discharges for the specified fiscal year. In this proposed rule, we are proposing the following HAC Reduction Program policies: (1) Establishing NHSN CDC HAI data submission requirements for newly opened hospitals; (2) a clarification of data requirements for Domain 1 scoring; (3) establishing performance periods for the FY 2018 and FY 2019 HAC Reduction Programs, including revising our regulations to accommodate variable timeframes; (4) adopting the refined PSI 90: Patient Safety and Adverse Events Composite (NQF #0531); and (5) changing the program scoring methodology from the current decile-based scoring to a continuous scoring methodology.

f. DSH Payment Adjustment and Additional Payment for Uncompensated Care

Section 3133 of the Affordable Care Act modified the Medicare disproportionate share hospital (DSH) payment methodology beginning in FY

2014. Under section 1886(r) of the Act, which was added by section 3133 of the Affordable Care Act, starting in FY 2014, DSHs will receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments in section 1886(d)(5)(F) of the Act. The remaining amount, equal to 75 percent of what otherwise would have been paid as Medicare DSH payments, will be paid as additional payments after the amount is reduced for changes in the percentage of individuals that are uninsured. Each Medicare DSH will receive an additional payment based on its share of the total amount of uncompensated care for all Medicare DSHs for a given time period.

In this proposed rule, we are proposing to update our estimates of the three factors used to determine uncompensated care payments for FY 2017 and proposing to continue our methodology of using a hospital's share of insured low-income days for purposes of determining Factor 3. For Puerto Rico hospitals, we are proposing to use 14 percent of Medicaid days as a proxy for SSI days in the calculation of Factor 3. We are proposing to continue to use the methodology we established in FY 2015 to calculate the uncompensated care payment amounts for merged hospitals such that we combine uncompensated care data for the hospitals that have undergone a merger in order to calculate their relative share of uncompensated care. We are proposing to expand the time period of the data used to calculate the uncompensated care payment amounts to be distributed, from one cost reporting period to three cost reporting periods. We also are proposing a future transition to using Worksheet S–10 data to determine the amounts and distribution of uncompensated care payments. Specifically, we are proposing a 3-year transition beginning in FY 2018 where we use a combination of Worksheet S–10 and proxy data until FY 2020 when all data used in computing the uncompensated care payment amounts to be distributed would come from Worksheet S–10.

g. Payments for Capital-Related Costs for Hospitals Located in Puerto Rico

Capital IPPS payments to hospitals located in Puerto Rico are currently computed based on a blend of 25 percent of the capital IPPS Puerto Rico rate and 75 percent of the capital IPPS Federal rate. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) increased the applicable Federal percentage of the operating IPPS payment for hospitals located in Puerto Rico from 75 percent to 100 percent and decreased the applicable Puerto Rico percentage of the operating IPPS payments for hospitals located in Puerto Rico from 25 percent to zero percent, applicable to discharges occurring on or after January 1, 2016. In this proposed rule, we are proposing to revise the calculation of capital IPPS payments to hospitals located in Puerto Rico to parallel the change in the statutory calculation of operating IPPS payments to hospitals located in Puerto Rico, beginning in FY 2017.

h. Proposed Changes to the LTCH PPS

In this proposed rule, we are proposing to revise and rebase the market basket used under the LTCH PPS (currently the 2009-based LTCH-specific market basket) to reflect a 2013 base year. In addition, in this proposed rule, we are proposing to change our 25-percent threshold policy by proposing to sunset our existing regulations at 42 CFR 412.534 and 412.536 and replace them with a single consolidated 25-percent threshold policy at proposed § 412.538. We also are proposing to change our existing regulations limiting allowable charges to beneficiaries for Subclause (II) LTCHs and proposing to make technical corrections to § 412.503.

i. Hospital Inpatient Quality Reporting (IQR) Program

Under section 1886(b)(3)(B)(viii) of the Act, hospitals are required to report data on measures selected by the Secretary for the Hospital IQR Program in order to receive the full annual percentage increase in payments. In past years, we have established measures for reporting data and the process for submittal and validation of the data.

In this proposed rule, we are making several proposals. First, we are proposing to remove 15 measures for the FY 2019 payment determination and subsequent years. Thirteen of these measures are electronic clinical quality measures (eCQMs), two of which we are proposing also to remove in their chart-abstracted form, because they are "topped-out," and two others are structural measures.

Second, we are proposing to refine two previously adopted measures beginning with the FY 2018 payment determination: (1) The Hospital-level, Risk-standardized Payment Associated with a 30-day Episode-of-Care for Pneumonia (NQF #2579); and (2) the Patient Safety and Adverse Events Composite (NQF #0531).

Third, we are proposing to add four new claims-based measures: (1) Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure; (2) Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure; (3) Spinal Fusion Clinical Episode-Based Payment Measure; and (4) Excess Days in Acute Care after Hospitalization for Pneumonia for the FY 2019 payment determination and subsequent years.

Fourth, we are inviting public comment on potential new quality measures under consideration for future inclusion in the Hospital IQR Program: (1) A refined version of the NIH Stroke Scale for the Hospital 30-Day Mortality Following Acute Ischemic Stroke Hospitalization Measure beginning as early as the FY 2022 payment determination; (2) the National Healthcare Safety Network (NHSN) Antimicrobial Use Measure (NQF #2720); and (3) one or more measures of behavioral health for the inpatient hospital setting, including measures previously adopted for the IPFQR Program (80 FR 46417). Also, we are seeking public comment on the possibility of future stratification of Hospital IQR Program data by race, ethnicity, sex, and disability on *Hospital Compare*, as well as on potential future hospital quality measures that incorporate health equity.

Fifth, we are proposing to require hospitals to submit all available eCQMs included in the Hospital IQR Program measure set for four quarters of data, on an annual basis, beginning with the CY 2017 reporting period/FY 2019 payment determination, in order to align the Hospital IQR Program with the Medicare and Medicaid EHR Incentive Programs. Also, we are proposing related eCQM submission requirements beginning with the FY 2019 payment determination.

Sixth, we are proposing to modify the existing validation process for Hospital IQR Program data to include validation of eCQMs beginning with the FY 2020 payment determination.

Seventh, we are proposing to update our Extraordinary Circumstances Extensions or Exemptions (ECE) policy by: (1) Extending the ECE request deadline for non-eCQM circumstances from 30 to 90 calendar days following an extraordinary circumstance, beginning in FY 2017 as related to extraordinary circumstance events that occur on or after October 1, 2016; and (2) establishing a separate submission deadline of April 1 following the end of the reporting calendar year for ECEs related to eCQMs beginning with an April 1, 2017 deadline and applying for subsequent eCQM reporting years.

j. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

Section 3004(a) of the Affordable Care Act amended section 1886(m)(5) of the Act to require the Secretary to establish the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). This program applies to all hospitals certified by Medicare as LTCHs. Beginning with the FY 2014 payment determination and subsequent years, the Secretary is required to reduce any annual update to the LTCH PPS standard Federal rate for discharges occurring during such fiscal year by 2 percentage points for any LTCH that does not comply with the requirements established by the Secretary.

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) amended the Act in ways that affect the LTCH QRP. Specifically, section 2(a) of the IMPACT Act amended title XVIII of the Act by adding section 1899B, titled Standardized Post-Acute Care (PAC) Assessment Data for Quality, Payment, and Discharge Planning. The Act requires that each LTCH submit, for FYs beginning on or after the specified application date (as defined in section 1899B(a)(2)(E) of the Act), data on quality measures specified under section 1899B(c)(1) of the Act and data on resource use and other measures specified under section 1899B(d)(1) of the Act in a manner and within the timeframes specified by the Secretary. In addition, each LTCH is required to submit standardized patient assessment data required under section 1899B(b)(1) of the Act in a manner and within the timeframes specified by the Secretary. Sections 1899B(c)(1) and 1899B(d)(1) of the Act require the Secretary to specify quality measures and resource use and other measures with respect to certain domains no later than the specified application date in section 1899B(a)(2)(E) of the Act that applies to each measure domain and PAC provider setting.

In this proposed rule, we are proposing three new measures for the FY 2018 payment determination and subsequent years to meet the requirements as set forth by the IMPACT Act. These proposed measures are: (1) MSPB–PAC LTCH QRP; (2) Discharge to Community-PAC LTCH QRP; and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for the PAC LTCH QRP. We also are proposing one new quality measure to meet the requirements of the IMPACT Act for the FY 2020 determination and subsequent years. The proposed measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, addresses the IMPACT Act domain of Medication Reconciliation.

In addition, we will publicly report LTCH quality data beginning in fall 2016, on a CMS Web site, such as *Hospital Compare*. We will initially publicly report quality data on four quality measures. In this proposed rule, we are proposing to publicly report data in 2017 on four additional measures. We are proposing additional details regarding procedures that would allow individual LTCHs to review and correct their data and information on measures that are to be made public before those measure data are made public. We also are proposing to provide confidential feedback reports to LTCHs on their performance on the specified measures, beginning 1 year after the specified application date that applies to such measures and LTCHs.

Finally, we are proposing to change the timing for submission of exception and extension requests from 30 days to 90 days from the date of the qualifying event which is preventing an LTCH from submitting their quality data for the LTCH QRP.

k. Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program

Section 1886(s)(4) of the Act, as added and amended by sections 3401(f) and 10322(a) of the Affordable Care Act, requires the Secretary to implement a quality reporting program for inpatient psychiatric hospitals and psychiatric units. Section 1886(s)(4)(C) of the Act requires that, for FY 2014 (October 1, 2013 through September 30, 2014) and each subsequent year, each psychiatric hospital and psychiatric unit must submit to the Secretary data on quality measures as specified by the Secretary. The data must be submitted in a form and manner and at a time specified by the Secretary. In this proposed rule, for the IPFQR Program, we are making several proposals. We are proposing two new measures beginning with the FY 2019 payment determination:

- SUB–3 Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB–3a Alcohol and Other Drug Use Disorder Treatment at Discharge (NQF #1664); and
- Thirty-day all-cause unplanned readmission following psychiatric hospitalization in an IPF.

We also are proposing a technical update to the previously finalized measure, "Screening for Metabolic Disorder." In addition, we are proposing to no longer specify in rulemaking the date of the public display of the program's data or that the preview period will be approximately 12 weeks before the public display date.

3. Summary of Costs and Benefits

- Adjustment for MS–DRG Documentation and Coding Changes. We are proposing to make a −1.5 percent recoupment adjustment to the standardized amount for FY 2017 to implement, in part, the requirement of section 631 of the ATRA that the Secretary make an adjustment totaling $11 billion over a 4-year period of FYs 2014, 2015, 2016, and 2017. This recoupment adjustment represents the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013. Prior to the ATRA, this amount could not have been recovered under Public Law 110–90.

While our actuaries estimated that a −9.3 percent recoupment adjustment to the standardized amount would be necessary if CMS were to fully recover the $11 billion recoupment required by section 631 of the ATRA in FY 2014, it is often our practice to delay or phase in rate adjustments over more than one year, in order to moderate the effects on rates in any one year. Taking into account the cumulative effects of this proposed adjustment and the adjustments made in FYs 2014, 2015, and 2016, we estimate that we would recover the full $11 billion required under section 631 of the ATRA by the end of FY 2017. We note that section 414 of the MACRA (Pub. L. 114–10), enacted on April 16, 2015, requires us to not make the single positive adjustment we intended to make in FY 2018, but instead make a 0.5 percent positive adjustment for each of FYs 2018 through 2023. The provision under section 414 of the MACRA does not impact our proposed FY 2017 recoupment adjustment, and we will address this MACRA provision in future rulemaking.

- Proposed Adjustment to IPPS Payment Rates as a Result of the 2-Midnight Policy. The proposed adjustment to IPPS rates resulting from the 2-midnight policy would increase IPPS payment rates by (1/0.998) * 1.006 for FY 2017. The 1.006 is a one-time factor that would be applied to the standardized amount, the hospital-specific rates, and the national capital Federal rate for FY 2017 only. Therefore, for FY 2018, we would apply a one-time factor of (1/1.006) in the calculation of the rates to remove this one-time prospective increase.
- Proposed Changes to the Hospital Readmissions Reduction Program. For FY 2017 and subsequent years, the

reduction is based on a hospital's risk-adjusted readmission rate during a 3-year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG). Overall, in this proposed rule, we estimate that 2,603 hospitals will have their base operating DRG payments reduced by their proposed proxy FY 2017 hospital-specific readmission adjustment. As a result, we estimate that the Hospital Readmissions Reduction Program will save approximately $532 million in FY 2017, an increase of approximately $100 million over the estimated FY 2016 savings. This increase in the estimated savings for the Hospital Readmissions Reduction Program in FY 2017 as compared to FY 2016 is primarily due to the inclusion of the refinement of the pneumonia readmissions measure, which expanded the measure cohort, along with the addition of the CABG readmission measure, in the calculation of the payment adjustment.

- Value-Based Incentive Payments under the Hospital VBP Program. We estimate that there will be no net financial impact to the Hospital VBP Program for the FY 2017 program year in the aggregate because, by law, the amount available for value-based incentive payments under the program in a given year must be equal to the total amount of base operating MS–DRG payment amount reductions for that year, as estimated by the Secretary. The estimated amount of base operating MS–DRG payment amount reductions for the FY 2017 program year and, therefore, the estimated amount available for value-based incentive payments for FY 2017 discharges is approximately $1.7 billion.
- Proposed Changes to the HAC Reduction Program. In regard to the five proposed changes to existing HAC Reduction Program policies described earlier, because a hospital's Total HAC score and its ranking in comparison to other hospitals in any given year depends on several different factors, any significant impact due to the HAC Reduction Program proposed changes for FY 2017, including which hospitals receive the adjustment, would depend on actual experience.
- Medicare DSH Payment Adjustment and Additional Payment for Uncompensated Care. Under section 1886(r) of the Act (as added by section 3133 of the Affordable Care Act), DSH payments to hospitals under section 1886(d)(5)(F) of the Act are reduced and an additional payment for uncompensated care is made to eligible hospitals beginning in FY 2014. Hospitals that receive Medicare DSH payments will receive 25 percent of the amount they previously would have received under the current statutory formula for Medicare DSH payments in section 1886(d)(5)(F) of the Act. The remainder, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, will be the basis for determining the additional payments for uncompensated care after the amount is reduced for changes in the percentage of individuals that are uninsured and additional statutory adjustments. Each hospital that receives Medicare DSH payments will receive an additional payment for uncompensated care based on its share of the total uncompensated care amount reported by Medicare DSHs. The reduction to Medicare DSH payments is not budget neutral.

For FY 2017, we are providing that the 75 percent of what otherwise would have been paid for Medicare DSH is adjusted to approximately 56.74 percent of the amount to reflect changes in the percentage of individuals that are uninsured and additional statutory adjustments. In other words, approximately 42.56 percent (the product of 75 percent and 56.74 percent) of our estimate of Medicare DSH payments, prior to the application of section 3133 of the Affordable Care Act, is available to make additional payments to hospitals for their relative share of the total amount of uncompensated care. We project that estimated Medicare DSH payments, and additional payments for uncompensated care made for FY 2017, would reduce payments overall by approximately 0.3 percent as compared to the estimate of Medicare DSH payments and uncompensated care payments that will be distributed in FY 2016. The additional payments have redistributive effects based on a hospital's uncompensated care amount relative to the uncompensated care amount for all hospitals that are estimated to receive Medicare DSH payments, and the proposed payment amount is not directly tied to a hospital's number of discharges.

- Proposed Update to the LTCH PPS Payment Rates and Other Payment Factors. Based on the best available data for the 419 LTCHs in our data base, we estimate that the proposed changes to the payment rates and factors that we are presenting in the preamble and Addendum of this proposed rule, which includes the second year under the transition of the statutory application of the new site neutral payment rate required by section 1886(m)(6)(A) of the Act, the proposed update to the LTCH PPS standard Federal payment rate for FY 2017, the proposed update to the LTCH PPS adjustment for differences in area wage levels (which includes the proposed update to the labor-related share based on the proposed revised and rebased LTCH PPS market basket) and estimated changes to the site neutral payment rate and short-stay outlier (SSO) and high-cost outlier (HCO) payments would result in an estimated decrease in payments from FY 2016 of approximately $355 million.
- Hospital Inpatient Quality Reporting (IQR) Program. In this proposed rule, we are proposing to remove 15 measures for the FY 2019 payment determination and subsequent years. We are proposing to add four new claims-based measures to the Hospital IQR Program for the FY 2019 payment determination and subsequent years. We also are proposing to require hospitals to report on all Hospital IQR Program electronic clinical quality measures that align with the Medicare EHR Incentive Program for four quarters of data on an annual basis for the FY 2019 payment determination and subsequent years. In addition, we are proposing to modify the existing validation process for the Hospital IQR Program data to include a random sample of up to 200 hospitals for validation of eCQMs. We estimate that our policies for the adoption and removal of measures will result in total hospital costs of $30 million across 3,300 IPPS hospitals.
- Proposed Changes Related to the LTCH QRP. In this proposed rule, we are proposing four quality measures for the LTCH QRP. We estimate that the total cost related to one of these proposed measures, the Drug Regimen Review Conducted with Follow-up for Identified Issues-PAC measure, would be $3,080 per LTCH annually, or $1,330,721 for all LTCHs annually. We also estimate that while there will be some additional burden associated with our proposal to expand data collection for the measure NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (77 FR 53624 through 53627), this burden has been previously accounted for in PRA submissions approved under OMB control number 0938–1163. For a detailed explanation, we refer readers to section I.M. of Appendix A (Economic Analyses) of this proposed rule. There is no additional burden for the three other claims-based measures proposed for adoption. Overall, we estimate the total cost for the 13 previously adopted measures and the four proposed new

measures would be $27,905 per LTCH annually or $12,054,724 for all LTCHs annually. These estimates were based on 432 LTCHs that are currently certified by Medicare. This is an average increase of 14 percent over the burden for FY 2016. This increase includes all quality measures that LTCHs are required to report, with the exception of the four proposed measures for FY 2017. Section VIII.C. of this proposed rule includes a detailed discussion of the policies.

- Proposed Changes to the IPFQR Program. In this proposed rule, we are proposing to add two new measures beginning with the FY 2019 payment determination and for subsequent years. One of these measures, the 30-Day All-Cause Unplanned Readmissions following Psychiatric Hospitalization in an Inpatient Psychiatric Facility measure, is calculated from administrative claims data. For the second measure, we estimate that our proposed policies would result in total costs of $11,834,748 for 1,684 IPFs nationwide.

B. Summary

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

Section 1886(d) of the Social Security Act (the Act) sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires the Secretary to use a prospective payment system (PPS) to pay for the capital-related costs of inpatient hospital services for these "subsection (d) hospitals." Under these PPSs, Medicare payment for hospital inpatient operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. Discharges are classified according to a list of diagnosis-related groups (DRGs).

The base payment rate is comprised of a standardized amount that is divided into a labor-related share and a nonlabor-related share. The labor-related share is adjusted by the wage index applicable to the area where the hospital is located. If the hospital is located in Alaska or Hawaii, the nonlabor-related share is adjusted by a cost-of-living adjustment factor. This base payment rate is multiplied by the DRG relative weight.

If the hospital treats a high percentage of certain low-income patients, it receives a percentage add-on payment applied to the DRG-adjusted base payment rate. This add-on payment, known as the disproportionate share hospital (DSH) adjustment, provides for a percentage increase in Medicare payments to hospitals that qualify under either of two statutory formulas designed to identify hospitals that serve a disproportionate share of low-income patients. For qualifying hospitals, the amount of this adjustment varies based on the outcome of the statutory calculations. The Affordable Care Act revised the Medicare DSH payment methodology and provides for a new additional Medicare payment that considers the amount of uncompensated care beginning on October 1, 2013.

If the hospital is training residents in an approved residency program(s), it receives a percentage add-on payment for each case paid under the IPPS, known as the indirect medical education (IME) adjustment. This percentage varies, depending on the ratio of residents to beds.

Additional payments may be made for cases that involve new technologies or medical services that have been approved for special add-on payments. To qualify, a new technology or medical service must demonstrate that it is a substantial clinical improvement over technologies or services otherwise available, and that, absent an add-on payment, it would be inadequately paid under the regular DRG payment.

The costs incurred by the hospital for a case are evaluated to determine whether the hospital is eligible for an additional payment as an outlier case. This additional payment is designed to protect the hospital from large financial losses due to unusually expensive cases. Any eligible outlier payment is added to the DRG-adjusted base payment rate, plus any DSH, IME, and new technology or medical service add-on adjustments.

Although payments to most hospitals under the IPPS are made on the basis of the standardized amounts, some categories of hospitals are paid in whole or in part based on their hospital-specific rate, which is determined from their costs in a base year. For example, sole community hospitals (SCHs) receive the higher of a hospital-specific rate based on their costs in a base year (the highest of FY 1982, FY 1987, FY 1996, or FY 2006) or the IPPS Federal rate based on the standardized amount. SCHs are the sole source of care in their areas. Specifically, section 1886(d)(5)(D)(iii) of the Act defines an SCH as a hospital that is located more than 35 road miles from another hospital or that, by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of hospital inpatient services reasonably available to Medicare beneficiaries. In addition, certain rural hospitals previously designated by the Secretary as essential access community hospitals are considered SCHs.

Under current law, the Medicare-dependent, small rural hospital (MDH) program is effective through FY 2017. Through and including FY 2006, an MDH received the higher of the Federal rate or the Federal rate plus 50 percent of the amount by which the Federal rate was exceeded by the higher of its FY 1982 or FY 1987 hospital-specific rate. For discharges occurring on or after October 1, 2007, but before October 1, 2017, an MDH receives the higher of the Federal rate or the Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the highest of its FY 1982, FY 1987, or FY 2002 hospital-specific rate. MDHs are a major source of care for Medicare beneficiaries in their areas. Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area, has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (not less than 60 percent of its inpatient days or discharges in its cost reporting year beginning in FY 1987 or in two of its three most recently settled Medicare cost reporting years).

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient hospital services "in accordance with a prospective payment system established by the Secretary." The basic methodology for determining capital prospective payments is set forth in our regulations at 42 CFR 412.308 and 412.312. Under the capital IPPS, payments are adjusted by the same DRG for the case as they are under the operating IPPS. Capital IPPS payments are also adjusted for IME and DSH, similar to the adjustments made under the operating IPPS. In addition, hospitals may receive outlier payments for those cases that have unusually high costs.

The existing regulations governing payments to hospitals under the IPPS are located in 42 CFR part 412, subparts A through M.

2. Hospitals and Hospital Units Excluded From the IPPS

Under section 1886(d)(1)(B) of the Act, as amended, certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Inpatient rehabilitation facility (IRF) hospitals and units; long-term care hospitals (LTCHs); psychiatric hospitals and units; children's hospitals; and cancer hospitals. Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS. Various sections of the Balanced Budget Act of

1997 (BBA, Pub. L. 105–33), the Medicare, Medicaid and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106–113), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. 106–554) provide for the implementation of PPSs for IRF hospitals and units, LTCHs, and psychiatric hospitals and units (referred to as inpatient psychiatric facilities (IPFs)). (We note that the annual updates to the LTCH PPS are now included as part of the IPPS annual update document. Updates to the IRF PPS and IPF PPS are issued as separate documents.) Children's hospitals, cancer hospitals, and RNHCIs continue to be paid solely under a reasonable cost-based system subject to a rate-of-increase ceiling on inpatient operating costs.

The existing regulations governing payments to excluded hospitals and hospital units are located in 42 CFR parts 412 and 413.

3. Long-Term Care Hospital Prospective Payment System (LTCH PPS)

The Medicare prospective payment system (PPS) for LTCHs applies to hospitals described in section 1886(d)(1)(B)(iv) of the Act effective for cost reporting periods beginning on or after October 1, 2002. The LTCH PPS was established under the authority of sections 123 of the BBRA and section 307(b) of the BIPA (as codified under section 1886(m)(1) of the Act). During the 5-year (optional) transition period, a LTCH's payment under the PPS was based on an increasing proportion of the LTCH Federal rate with a corresponding decreasing proportion based on reasonable cost principles. Effective for cost reporting periods beginning on or after October 1, 2006, all LTCHs are paid 100 percent of the Federal rate. Section 1206(a) of Public Law 113–67 established the site neutral payment rate under the LTCH PPS, which made the LTCH PPS a dual rate payment system beginning in FY 2016. Under this statute, based on a rolling effective date that is linked to the date on which a given LTCH's Federal FY 2016 cost reporting period begins, LTCHs are paid for LTCH discharges at the site neutral payment rate unless the discharge meets the patient criteria for payment at the LTCH PPS standard Federal payment rate. The existing regulations governing payment under the LTCH PPS are located in 42 CFR part 412, subpart O. Beginning October 1, 2009, we issue the annual updates to the LTCH PPS in the same documents that update the IPPS (73 FR 26797 through 26798).

4. Critical Access Hospitals (CAHs)

Under sections 1814(l), 1820, and 1834(g) of the Act, payments made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services are generally based on 101 percent of reasonable cost. Reasonable cost is determined under the provisions of section 1861(v)(1)(A) of the Act and existing regulations under 42 CFR parts 413 and 415.

5. Payments for Graduate Medical Education (GME)

Under section 1886(a)(4) of the Act, costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act. The amount of payment for direct GME costs for a cost reporting period is based on the hospital's number of residents in that period and the hospital's costs per resident in a base year. The existing regulations governing payments to the various types of hospitals are located in 42 CFR part 413.

C. Summary of Provisions of Recent Legislation Proposed To Be Implemented in This Proposed Rule

1. American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240)

The American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240), enacted on January 2, 2013, made a number of changes that affect the IPPS. In this proposed rule, we are proposing to make policy changes to implement section 631 of the American Taxpayer Relief Act of 2012, which amended section 7(b)(1)(B) of Public Law 110–90 and requires a recoupment adjustment to the standardized amounts under section 1886(d) of the Act based upon the Secretary's estimates for discharges occurring in FY 2014 through FY 2017 to fully offset $11 billion (which represents the amount of the increase in aggregate payments from FYs 2008 through 2013 for which an adjustment was not previously applied).

2. Pathway for SGR Reform Act of 2013 (Pub. L. 113–67)

The Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) introduced new payment rules in the LTCH PPS. Under section 1206 of this law, discharges in cost reporting periods beginning on or after October 1, 2015 under the LTCH PPS will receive payment under a site neutral rate unless the discharge meets certain patient-specific criteria. In this proposed rule, we are providing clarifications to prior policy changes that implemented provisions under section 1206 of the Pathway for SGR Reform Act.

3. Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185)

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act (Pub. L. 113–185), enacted on October 6, 2014, made a number of changes that affect the Long-Term Care Quality Reporting Program (LTCH QRP). In this proposed rule, we are continuing to implement portions of section 1899B of the Act, as added by section 2 of the IMPACT Act, which, in part, requires LTCHs, among other postacute care providers, to report standardized patient assessment data, data on quality measures, and data on resource use and other measures.

4. The Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10)

The Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10) extended the MDH program and changes to the payment adjustment for low-volume hospitals through FY 2017. In this proposed rule, we are proposing to update the low-volume hospital payment adjustment for FY 2017 under the extension of the temporary changes to the low-volume hospital payment adjustment provided for by section 204 of Public Law 114–10. We also state our intention to finalize in the FY 2017 IPPS/LTCH PPS final rule the provisions of the FY 2016 IPPS/LTCH PPS interim final rule with comment period (80 FR 49594 through 49597) that implemented sections 204 and 205 of Public Law 114–10.

5. The Consolidated Appropriations Act, 2016 (Pub. L. 114–113)

The Consolidated Appropriations Act, 2016 (Pub. L. 114–113), enacted on December 18, 2015, made changes that affect the IPPS and the LTCH PPS. Section 231 of Public Law 114–113 provides for a temporary exception for certain wound care discharges from the application of the site neutral payment rate under the LTCH PPS for certain LTCHs, which is being implemented in an interim final rule with comment period. Section 601 of Public Law 114–113 made changes to the payment calculation for operating IPPS payments for hospitals located in Puerto Rico. Section 602 of Public Law 114–113 specifies that Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016, and also applies the adjustments to the applicable percentage increase under the statute for Puerto Rico hospitals that are not meaningful EHR users, effective FY 2022. In this proposed rule, we are proposing conforming changes to our regulations to reflect the provisions of section 601 of Public Law 114–113, which increased the applicable Federal percentage of the operating IPPS payment for hospitals located in Puerto Rico from 75 percent to 100 percent and decreased the applicable Puerto Rico percentage of the operating IPPS payments for hospitals located in Puerto Rico from 25 percent to zero percent, applicable to discharges occurring on or after January 1, 2016.

6. The Notice of Observation Treatment and Implication for Care Eligibility Act (the NOTICE Act) (Pub. L. 114–42)

The Notice of Observation Treatment and Implication for Care Eligibility Act (the NOTICE Act) (Pub. L. 114–42) enacted on August 6, 2015, amended section 1866(a)(1) of the Act by adding new subparagraph (Y) that requires hospitals and CAHs to provide written notification and an oral explanation of such notification to individuals receiving observation services as outpatients for more than 24 hours at the hospitals or CAHs. In this proposed rule, we are proposing to implement the provisions of Public Law 114–42.

D. Summary of the Provisions of This Proposed Rule

In this proposed rule, we are setting forth proposed payment and policy changes to the Medicare IPPS for FY 2017 operating costs and for capital-related costs of acute care hospitals and certain hospitals and hospital units that are excluded from IPPS, including proposed changes relating to payments for IME and direct GME to certain hospitals that continue to be excluded from the IPPS and paid on a reasonable cost basis. In addition, in this proposed rule, we are setting forth proposed changes to the payment rates, factors, and other payment and policy-related changes to programs associated with payment rate policies under the LTCH PPS for FY 2017.

Below is a summary of the major changes that we are proposing to make:

1. Proposed Changes to MS–DRG Classifications and Recalibrations of Relative Weights

In section II. of the preamble of the proposed rule, we include—

- Proposed changes to MS–DRG classifications based on our yearly review for FY 2017.
- Proposed application of the documentation and coding adjustment for FY 2017 resulting from implementation of the MS–DRG system.
- Proposed recalibrations of the MS–DRG relative weights.
- A discussion of the FY 2017 status of new technologies approved for add-on payments for FY 2016 and a presentation of our evaluation and analysis of the FY 2017 applicants for add-on payments for high-cost new medical services and technologies (including public input, as directed by Public Law 108–173, obtained in a town hall meeting).

2. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

In section III. of the preamble to this proposed rule, we are proposing revisions to the wage index for acute care hospitals and the annual update of the wage data. Specific issues addressed include, but not limited to, the following:

- The proposed FY 2017 wage index update using wage data from cost reporting periods beginning in FY 2013.
- Calculation of the proposed occupational mix adjustment for FY 2017 based on the 2013 Occupational Mix Survey.
- Analysis and implementation of the proposed FY 2017 occupational mix adjustment to the wage index for acute care hospitals.
- Proposed application of the rural floor, the proposed imputed floor, and the proposed frontier State floor.
- Transitional wage indexes relating to the continued use of the revised OMB labor market area delineations based on 2010 Decennial Census data.
- Proposed revisions to the wage index for acute care hospitals based on hospital redesignations and reclassifications under sections 1886(d)(8)(B), (d)(8)(E), and (d)(10) of the Act.
- Notification regarding proposed CMS "lock-in" date for urban to rural reclassifications under § 412.103.
- The proposed adjustment to the wage index for acute care hospitals for FY 2017 based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index.
- Determination of the labor-related share for the proposed FY 2017 wage index.
- Solicitation of Comments on Treatment of Overhead and Home Office Costs in the Wage Index Calculation

3. Other Decisions and Proposed Changes to the IPPS for Operating Costs and GME Costs

In section IV. of the preamble of this proposed rule, we discuss proposed changes or clarifications of a number of the provisions of the regulations in 42 CFR parts 412 and 413, including the following:

- Proposed conforming changes to our regulations to reflect the changes to operating payments for subsection (d) Puerto Rico hospitals in accordance with the provisions of section 601 of Public Law 114–113.
- Proposed changes to the inpatient hospital update for FY 2017.
- Proposed updated national and regional case-mix values and discharges for purposes of determining RRC status.
- Proposed payment adjustment for low-volume hospitals for FY 2017.
- The statutorily required IME adjustment factor for FY 2017.
- Proposed changes to the methodologies for determining Medicare DSH payments and the additional payments for uncompensated care.
- Proposed changes to the rules for payment adjustments under the Hospital Readmissions Reduction Program based on hospital readmission measures and the process for hospital review and correction of those rates for FY 2017.
- Proposed changes to the requirements and provision of value-based incentive payments under the Hospital Value-Based Purchasing Program for FY 2017.
- Proposed requirements for payment adjustments to hospitals under the HAC Reduction Program for FY 2017.
- Proposed changes relating to direct GME and IME payments to urban hospitals with rural track training programs.
- Discussion of the Rural Community Hospital Demonstration Program and a proposal for making a budget neutrality adjustment for the demonstration program.
- Proposed implementation of the Notice of Observation Treatment and Implications for Care Eligibility Act (the NOTICE Act) for hospitals and CAHs.
- Proposed technical changes and corrections to regulations relating to cost to related organizations and Medicare cost reports.

4. Proposed FY 2017 Policy Governing the IPPS for Capital-Related Costs

In section V. of the preamble to this proposed rule, we discuss the proposed payment policy requirements for capital-related costs and capital payments to hospitals for FY 2017. In addition, we discuss proposed changes to the calculation of capital IPPS payments to hospitals located in Puerto Rico to parallel the change in the statutory calculation of operating IPPS payments to hospitals located in Puerto Rico, beginning in FY 2017.

5. Proposed Changes to the Payment Rates for Certain Excluded Hospitals: Rate-of-Increase Percentages

In section VI. of the preamble of this proposed rule, we discuss—

- Proposed changes to payments to certain excluded hospitals for FY 2017.
- Proposed implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration.

6. Proposed Changes to the LTCH PPS

In section VII. of the preamble of this proposed rule, we set forth—

- Proposed changes to the LTCH PPS Federal payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2017.
- Proposals to sunset our existing 25-percent threshold policy regulations, and replace them with single consolidated 25 percent threshold policy regulation.
- Proposed changes to the limitation on charges (LOC) to beneficiaries and related billing requirements for "subclause (II)" LTCHs to align those LTCH PPS payment adjustment policies with the LOC policies applied in the TEFRA payment context.
- Proposed technical corrections to certain definitions to correct and clarify their use under the application of the site neutral payment rate and proposed additional definitions in accordance with our proposed modifications to the 25-percent policy.
- Proposed rebasing and revising of the LTCH market basket to update the LTCH PPS, effective for FY 2017.

7. Proposed Changes Relating to Quality Data Reporting for Specific Providers and Suppliers

In section VIII. of the preamble of the proposed rule, we address—

- Proposed requirements for the Hospital Inpatient Quality Reporting (IQR) Program as a condition for receiving the full applicable percentage increase.
- Proposed changes to the requirements for the quality reporting program for PPS-exempt cancer hospitals (PCHQR Program).
- Proposed changes to the requirements under the LTCH Quality Reporting Program (LTCH QRP).
- Proposed changes to the requirements under the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program.
- Proposed changes relating to clinical quality measures for the Medicare Electronic Health Record (EHR) Incentive Program and eligible hospitals and CAHs.

8. Determining Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits for Acute Care Hospitals

In the Addendum to this proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2017 prospective payment rates for operating costs and capital-related costs for acute care hospitals. We are proposing to establish the threshold amounts for outlier cases. In addition, we address the update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2017 for certain hospitals excluded from the IPPS.

9. Determining Prospective Payment Rates for LTCHs

In the Addendum to this proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2017 LTCH PPS standard Federal payment rate and other factors used to determine LTCH PPS payments under both the LTCH PPS standard Federal payment rate and the site neutral payment rate in FY 2017. We are proposing to establish the adjustments for wage levels, the labor-related share, the cost-of-living adjustment, and high-cost outliers, including the applicable fixed-loss amounts and the LTCH cost-to-charge ratios (CCRs) for both payment rates. We also are providing the estimated market basket update to apply to the ceiling used to determine payments under the existing payment adjustment for "subclause (II)" LTCHs for cost reporting periods beginning in FY 2017.

10. Impact Analysis

In Appendix A of this proposed rule, we set forth an analysis of the impact that the proposed changes would have on affected acute care hospitals, CAHs, LTCHs, PCHs, and IPFs.

11. Recommendation of Update Factors for Operating Cost Rates of Payment for Hospital Inpatient Services

In Appendix B of this proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we provided our recommendations of the appropriate percentage changes for FY 2017 for the following:

- A single average standardized amount for all areas for hospital inpatient services paid under the IPPS for operating costs of acute care hospitals (and hospital-specific rates applicable to SCHs and MDHs).
- Target rate-of-increase limits to the allowable operating costs of hospital inpatient services furnished by certain hospitals excluded from the IPPS.
- The LTCH PPS standard Federal payment rate and the site neutral payment rate for hospital inpatient services provided for LTCH PPS discharges.

12. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, MedPAC is required to submit a report to Congress, no later than March 15 of each year, in which MedPAC reviews and makes recommendations on Medicare payment policies. MedPAC's March 2016 recommendations concerning hospital inpatient payment policies address the update factor for hospital inpatient operating costs and capital-related costs for hospitals under the IPPS. We addressed these recommendations in Appendix B of this proposed rule. For further information relating specifically to the MedPAC March 2016 report or to obtain a copy of the report, contact MedPAC at (202) 220–3700 or visit MedPAC's Web site at: *http://www.medpac.gov.*

II. Proposed Changes to Medicare Severity Diagnosis-Related Group (MS–DRG) Classifications and Relative Weights

A. Background

Section 1886(d) of the Act specifies that the Secretary shall establish a classification system (referred to as diagnosis-related groups (DRGs)) for inpatient discharges and adjust payments under the IPPS based on appropriate weighting factors assigned to each DRG. Therefore, under the IPPS, Medicare pays for inpatient hospital services on a rate per discharge basis that varies according to the DRG to which a beneficiary's stay is assigned. The formula used to calculate payment for a specific case multiplies an individual hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG, relative to the average resources used to treat cases in all DRGs.

Congress recognized that it would be necessary to recalculate the DRG relative weights periodically to account for changes in resource consumption. Accordingly, section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually. These adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources.

B. MS–DRG Reclassifications

For general information about the MS–DRG system, including yearly reviews and changes to the MS–DRGs, we refer readers to the previous discussions in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43764 through 43766), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50053 through 50055), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51485 through 51487), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53273), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50512), the FY 2015 IPPS/LTCH PPS final rule (79 FR 49871), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49342).

C. Adoption of the MS–DRGs in FY 2008

For information on the adoption of the MS–DRGs in FY 2008, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189).

D. Proposed FY 2017 MS–DRG Documentation and Coding Adjustment

1. Background on the Prospective MS–DRG Documentation and Coding Adjustments for FY 2008 and FY 2009 Authorized by Public Law 110–90

In the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189), we adopted the MS–DRG patient classification system for the IPPS, effective October 1, 2007, to better recognize severity of illness in Medicare payment rates for acute care hospitals. The adoption of the MS–DRG system resulted in the expansion of the number of DRGs from 538 in FY 2007 to 745 in FY 2008. (Currently, for FY 2016, there are 756 MS–DRGs.) By increasing the number of MS–DRGs and more fully taking into account patient severity of illness in Medicare payment rates for acute care hospitals, MS–DRGs encourage hospitals to improve their documentation and coding of patient diagnoses.

In the FY 2008 IPPS final rule with comment period (72 FR 47175 through 47186), we indicated that the adoption of the MS–DRGs had the potential to lead to increases in aggregate payments without a corresponding increase in actual patient severity of illness due to the incentives for additional documentation and coding. In that final rule with comment period, we exercised our authority under section 1886(d)(3)(A)(vi) of the Act, which authorizes us to maintain budget neutrality by adjusting the national standardized amount, to eliminate the estimated effect of changes in coding or classification that do not reflect real changes in case-mix. Our actuaries estimated that maintaining budget neutrality required an adjustment of −4.8 percent to the national standardized amount. We provided for phasing in this −4.8 percent adjustment over 3 years. Specifically, we established prospective documentation and coding adjustments of −1.2 percent for FY 2008, −1.8 percent for FY 2009, and −1.8 percent for FY 2010.

On September 29, 2007, Congress enacted the TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007 (Pub. L. 110–90). Section 7(a) of Public Law 110–90 reduced the documentation and coding adjustment made as a result of the MS–DRG system that we adopted in the FY 2008 IPPS final rule with comment period to −0.6 percent for FY 2008 and −0.9 percent for FY 2009, and we finalized the FY 2008 adjustment through rulemaking, effective October 1, 2007 (72 FR 66886).

For FY 2009, section 7(a) of Public Law 110–90 required a documentation and coding adjustment of −0.9 percent, and we finalized that adjustment through rulemaking effective October 1, 2008 (73 FR 48447). The documentation and coding adjustments established in the FY 2008 IPPS final rule with comment period, which reflected the amendments made by section 7(a) of Public Law 110–90, are cumulative. As a result, the −0.9 percent documentation and coding adjustment for FY 2009 was in addition to the −0.6 percent adjustment for FY 2008, yielding a combined effect of −1.5 percent.

2. Adjustment to the Average Standardized Amounts Required by Public Law 110–90

a. Prospective Adjustment Required by Section 7(b)(1)(A) of Public Law 110–90

Section 7(b)(1)(A) of Public Law 110–90 requires that, if the Secretary determines that implementation of the MS–DRG system resulted in changes in documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 or FY 2009 that are different than the prospective documentation and coding adjustments applied under section 7(a) of Public Law 110–90, the Secretary shall make an appropriate adjustment under section 1886(d)(3)(A)(vi) of the Act.

Section 1886(d)(3)(A)(vi) of the Act authorizes adjustments to the average standardized amounts for subsequent fiscal years in order to eliminate the effect of such coding or classification changes. These adjustments are intended to ensure that future annual aggregate IPPS payments are the same as the payments that otherwise would have been made had the prospective adjustments for documentation and coding applied in FY 2008 and FY 2009 reflected the change that occurred in those years.

b. Recoupment or Repayment Adjustments in FYs 2010 Through 2012 Required by Section 7(b)(1)(B) Public Law 110–90

If, based on a retroactive evaluation of claims data, the Secretary determines that implementation of the MS–DRG system resulted in changes in documentation and coding that did not reflect real changes in case-mix for discharges occurring during FY 2008 or FY 2009 that are different from the prospective documentation and coding adjustments applied under section 7(a) of Public Law 110–90, section 7(b)(1)(B) of Public Law 110–90 requires the Secretary to make an additional adjustment to the standardized amounts under section 1886(d) of the Act. This adjustment must offset the estimated increase or decrease in aggregate payments for FYs 2008 and 2009 (including interest) resulting from the difference between the estimated actual documentation and coding effect and the documentation and coding adjustment applied under section 7(a) of Public Law 110–90. This adjustment is in addition to making an appropriate adjustment to the standardized amounts under section 1886(d)(3)(A)(vi) of the Act as required by section 7(b)(1)(A) of Public Law 110–90. That is, these adjustments are intended to recoup (or repay, in the case of underpayments) spending in excess of (or less than) spending that would have occurred had the prospective adjustments for changes in documentation and coding applied in FY 2008 and FY 2009 matched the changes that occurred in those years. Public Law 110–90 requires that the Secretary only make these recoupment or repayment adjustments for discharges occurring during FYs 2010, 2011, and 2012.

3. Retrospective Evaluation of FY 2008 and FY 2009 Claims Data

In order to implement the requirements of section 7 of Public Law 110–90, we performed a retrospective evaluation of the FY 2008 data for claims paid through December 2008 using the methodology first described in the FY 2009 IPPS/LTCH PPS final rule (73 FR 43768 and 43775) and later discussed in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43768 through 43772). We performed the same analysis for FY 2009 claims data using the same methodology as we did for FY 2008 claims (75 FR 50057 through 50068). The results of the analysis for the FY 2011 IPPS/LTCH PPS proposed and final rules, and subsequent evaluations in FY 2012, supported that the 5.4 percent estimate accurately reflected the FY 2009 increases in documentation and coding under the MS–DRG system. We were persuaded by both MedPAC's analysis (as discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50064 through 50065)) and our own review of the methodologies proposed by various commenters that the methodology we employed to determine the required documentation and coding adjustments was sound.

As in prior years, the FY 2008, FY 2009, and FY 2010 MedPAR files are available to the public to allow independent analysis of the FY 2008 and FY 2009 documentation and coding effects. Interested individuals may still order these files through the CMS Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/* by clicking on MedPAR Limited Data Set (LDS)—Hospital (National). This CMS Web page describes the file and provides directions and further detailed instructions for how to order.

Persons placing an order must send the following: A Letter of Request, the LDS Data Use Agreement and Research Protocol (refer to the Web site for further instructions), the LDS Form, and a check (refer to the Web site for the required payment amount) to:

Mailing address if using the U.S. Postal Service:

Centers for Medicare & Medicaid Services, RDDC Account, Accounting Division, P.O. Box 7520, Baltimore, MD 21207–0520.

Mailing address if using express mail:

Centers for Medicare & Medicaid Services, OFM/Division of Accounting—RDDC, 7500 Security Boulevard, C3–07–11, Baltimore, MD 21244–1850.

4. Prospective Adjustments for FY 2008 and FY 2009 Authorized by Section 7(b)(1)(A) of Public Law 110–90

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43767 through 43777), we opted to delay the implementation of any documentation and coding adjustment until a full analysis of case-mix changes based on FY 2009 claims data could be completed. We refer readers to the FY 2010 IPPS/RY LTCH PPS final rule for a detailed description of our proposal, responses to comments, and finalized policy. After analysis of the FY 2009 claims data for the FY 2011 IPPS/LTCH PPS final rule (75 FR 50057 through 50073), we found a total prospective documentation and coding effect of 5.4 percent. After accounting for the −0.6 percent and the −0.9 percent documentation and coding adjustments in FYs 2008 and 2009, we found a remaining documentation and coding effect of 3.9 percent. As we have discussed, an additional cumulative adjustment of −3.9 percent would be necessary to meet the requirements of section 7(b)(1)(A) of Public Law 110–90 to make an adjustment to the average standardized amounts in order to eliminate the full effect of the documentation and coding changes that do not reflect real changes in case-mix on future payments. Unlike section 7(b)(1)(B) of Public Law 110–90, section 7(b)(1)(A) does not specify when we must apply the prospective adjustment, but merely requires us to make an "appropriate" adjustment. Therefore, as we stated in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50061), we believed the law provided some discretion as to the manner in which we applied the prospective adjustment of −3.9 percent. As we discussed extensively in the FY 2011 IPPS/LTCH PPS final rule, it has been our practice to moderate payment adjustments when necessary to mitigate the effects of significant downward adjustments on hospitals, to avoid what could be widespread, disruptive effects of such adjustments on hospitals. Therefore, we stated that we believed it was appropriate to not implement the −3.9 percent prospective adjustment in FY 2011 because we finalized a −2.9 percent recoupment adjustment for that fiscal year. Accordingly, we did not propose a prospective adjustment under section 7(b)(1)(A) of Public Law 110–90 for FY 2011 (75 FR 23868 through 23870). We noted that, as a result, payments in FY 2011 (and in each future fiscal year until we implemented the requisite adjustment) would be higher than they would have been if we had implemented an adjustment under section 7(b)(1)(A) of Public Law 110–90.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51489 and 51497), we indicated that, because further delay of this prospective adjustment would result in a continued accrual of unrecoverable overpayments, it was imperative that we implement a prospective adjustment for FY 2012, while recognizing CMS' continued desire to mitigate the effects of any significant downward adjustments to hospitals. Therefore, we implemented a −2.0 percent prospective adjustment to the standardized amount instead of the full −3.9 percent.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53274 through 53276), we completed the prospective portion of the adjustment required under section 7(b)(1)(A) of Public Law 110–90 by finalizing a −1.9 percent adjustment to the standardized amount for FY 2013. We stated that this adjustment would remove the remaining effect of the documentation and coding changes that do not reflect real changes in case-mix that occurred in FY 2008 and FY 2009. We believed that it was imperative to implement the full remaining adjustment, as any further delay would result in an overstated standardized amount in FY 2013 and any future fiscal years until a full adjustment was made.

We noted again that delaying full implementation of the prospective portion of the adjustment required under section 7(b)(1)(A) of Public Law 110–90 until FY 2013 resulted in payments in FY 2010 through FY 2012 being overstated. These overpayments could not be recovered by CMS, as section 7(b)(1)(B) of Public Law 110–90 limited recoupments to overpayments made in FY 2008 and FY 2009.

5. Recoupment or Repayment Adjustment Authorized by Section 7(b)(1)(B) of Public Law 110–90

Section 7(b)(1)(B) of Public Law 110–90 requires the Secretary to make an adjustment to the standardized amounts under section 1886(d) of the Act to offset the estimated increase or decrease in aggregate payments for FY 2008 and FY 2009 (including interest) resulting from the difference between the estimated actual documentation and coding effect and the documentation and coding adjustments applied under section 7(a) of Public Law 110–90. This determination must be based on a retrospective evaluation of claims data. Our actuaries estimated that there was a 5.8 percentage point difference resulting in an increase in aggregate payments of approximately $6.9 billion. Therefore, as discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50062 through 50067), we determined that an aggregate adjustment of −5.8 percent in FYs 2011 and 2012 would be necessary in order to meet the requirements of section 7(b)(1)(B) of Public Law 110–90 to adjust the standardized amounts for discharges occurring in FYs 2010, 2011, and/or 2012 to offset the estimated amount of the increase in aggregate payments (including interest) in FYs 2008 and 2009.

It is often our practice to phase in payment rate adjustments over more than one year in order to moderate the effect on payment rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, in the FY 2011 IPPS/LTCH PPS final rule, we made an adjustment to the standardized amount of −2.9 percent, representing approximately half of the aggregate adjustment required under section 7(b)(1)(B) of Public Law 110–90, for FY 2011. An adjustment of this magnitude allowed us to moderate the effects on hospitals in one year while simultaneously making it possible to implement the entire adjustment within the timeframe required under section 7(b)(1)(B) of Public Law 110–90 (that is, no later than FY 2012). For FY 2012, in accordance with the timeframes set forth by section 7(b)(1)(B) of Public Law 110–90, and consistent with the discussion in the FY 2011 IPPS/LTCH PPS final rule, we completed the recoupment adjustment by implementing the remaining −2.9 percent adjustment, in addition to removing the effect of the −2.9 percent adjustment to the standardized amount finalized for FY 2011 (76 FR 51489 and 51498). Because these adjustments, in effect, balanced out, there was no year-to-year change in the standardized amount due to this recoupment adjustment for FY 2012. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53276), we made a final +2.9 percent adjustment to the standardized amount, completing the recoupment portion of section 7(b)(1)(B) of Public Law 110–90. We note that with this positive adjustment, according to our estimates, all overpayments made in FY 2008 and FY 2009 have been fully recaptured with appropriate interest, and the standardized amount has been returned to the appropriate baseline.

6. Proposed Recoupment or Repayment Adjustment Authorized by Section 631 of the American Taxpayer Relief Act of 2012 (ATRA)

Section 631 of the ATRA amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment or adjustments totaling $11 billion by FY 2017. This adjustment represents the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013. As discussed earlier, this delay in implementation resulted in overstated payment rates in FYs 2010, 2011, and 2012. The resulting overpayments could not have been recovered under Public Law 110–90.

Similar to the adjustments authorized under section 7(b)(1)(B) of Public Law 110–90, the adjustment required under section 631 of the ATRA is a one-time recoupment of a prior overpayment, not a permanent reduction to payment rates. Therefore, we anticipated that any adjustment made to reduce payment rates in one year would eventually be offset by a positive adjustment in 2018, once the necessary amount of overpayment was recovered. However, section 414 of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, Public Law 114–10, enacted on April 16, 2015, replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percent positive adjustment for each of FYs 2018 through 2023. We stated in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49345) that we will address this MACRA provision in future rulemaking.

As we stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50515 through 50517), our actuaries estimate that a −9.3 percent adjustment to the standardized amount would be necessary if CMS were to fully recover the $11 billion recoupment required by section 631 of the ATRA in FY 2014. It is often our practice to phase in payment rate adjustments over more than one year, in order to moderate the effect on payment rates in any one year. Therefore, consistent with the policies that we have adopted in many similar cases, and after consideration of the public comments we received, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50515 through 50517), we implemented a −0.8 percent recoupment adjustment to the standardized amount in FY 2014. We stated that if adjustments of approximately −0.8 percent are implemented in FYs 2014, 2015, 2016, and 2017, using standard inflation factors, we estimate that the entire $11 billion will be accounted for by the end of the statutory 4-year timeline. As estimates of any future adjustments are subject to slight variations in total savings, we did not provide for specific adjustments for FYs 2015, 2016, or 2017 at that time. We stated that we believed that this level of adjustment for FY 2014 was a reasonable and fair approach that satisfies the requirements of the statute while mitigating extreme annual fluctuations in payment rates.

Consistent with the approach discussed in the FY 2014 rulemaking for recouping the $11 billion required by section 631 of the ATRA, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49874) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49345), we implemented additional −0.8 percent recoupment adjustments to the standardized amount in FY 2015 and FY 2016, respectively. We estimated that these adjustments, combined with leaving the prior −0.8 percent adjustments in place, would recover up to $2 billion in FY 2015 and another $3 billion in FY 2016. When combined with the approximately $1 billion adjustment made in FY 2014, we estimated that approximately $5 to $6 billion would be left to recover under section 631 of the ATRA by the end of FY 2016.

However, due to lower than previously estimated inpatient spending, an adjustment of −0.8 percent in FY 2017 would not recoup the $11 billion under section 631 of the ATRA. Based on the FY 2017 President's Budget, our actuaries currently estimate that FY 2014 through FY 2016 spending subject to the documentation and coding recoupment adjustment in the absence of the −0.8 percent adjustments made in FYs 2014 through 2016 would have been $123.783 billion in FY 2014, $124.361 billion in FY 2015, and $127.060 billion in FY 2016. As shown in the following table, the amount recouped in each of those fiscal years is therefore calculated as the difference between those amounts and the amounts determined to have been spent in those years with the −0.8 percent adjustment applied, namely $122.801 billion in FY 2014, $122.395 billion in FY 2015, and $124.059 billion in FY 2016. This yields an estimated total recoupment through the end of FY 2016 of $5.950 billion.

RECOUPMENT MADE UNDER SECTION 631 OF THE AMERICAN TAXPAYER RELIEF ACT OF 2012 (ATRA)

	IPPS Spending* (billions)	Cumulative adjustment factor	Adjusted IPPS spending (billions)	Recoupment amount (billions)
FY 2014	$122.801	1.00800	$123.783	$0.98

RECOUPMENT MADE UNDER SECTION 631 OF THE AMERICAN TAXPAYER RELIEF ACT OF 2012 (ATRA)—Continued

	IPPS Spending * (billions)	Cumulative adjustment factor	Adjusted IPPS spending (billions)	Recoupment amount (billions)
FY 2015	122.395	1.01606	124.361	1.97
FY 2016	124.059	1.02419	127.060	3.00
Total				5.95

* Based on FY 2017 President's Budget, including capital, IME, and DSH payments.

These estimates and the estimate of FY 2017 spending subject to the documentation and coding recoupment adjustment also will be contained in a memorandum from the Office of the Actuary that we will make publicly available on the CMS Web site. A description of the President's Budget for FY 2017 is currently available on the OMB Web site at: *https://www.whitehouse.gov/omb/budget.*

Our actuaries currently estimate that the FY 2017 spending subject to the documentation and coding recoupment adjustment (including capital, IME, and DSH payment) would be $129.625 billion in the absence of any documentation and recoupment adjustments from FY 2014 through FY 2017. Therefore, our actuaries currently estimate that, to the nearest tenth of a percent, the FY 2017 documentation and coding adjustment factor that will recoup as closely as possible $11 billion from FY 2014 through FY 2017 without exceeding this amount is −1.5 percent. This adjustment factor yields an estimated spending amount in FY 2017 of $124.693 billion, calculated as $129.625/(1.008*1.008*1.008*1.015). This estimated −1.5 percent adjustment factor will be updated for the final rule based on the FY 2017 President's Budget Midsession Review. It is possible that, based on updated estimates, the necessary adjustment factor to the nearest tenth of a percent could be different than our actuaries' current estimate of −1.5 percent. The proposed −1.5 percent adjustment would be the final adjustment required under section 631 of the ATRA, and when combined with the effects of previous adjustments made in FY 2014, FY 2015, and FY 2016, we estimate will satisfy the section 631 of the ATRA recoupment. As stated earlier, once the recoupment was complete, we had anticipated making a single positive adjustment in FY 2018 to offset the reductions required to recoup the $11 billion under section 631 of the ATRA. However, as stated earlier, section 414 of the MACRA requires that we not make the single positive adjustment we intended to make in FY 2018, but instead make a 0.5 percent positive adjustment for each of FYs 2018 through 2023. The provision under section 414 of the MACRA does not impact our proposed FY 2017 adjustment, and we will address this MACRA provision in future rulemaking.

E. Refinement of the MS–DRG Relative Weight Calculation

1. Background

Beginning in FY 2007, we implemented relative weights for DRGs based on cost report data instead of charge information. We refer readers to the FY 2007 IPPS final rule (71 FR 47882) for a detailed discussion of our final policy for calculating the cost-based DRG relative weights and to the FY 2008 IPPS final rule with comment period (72 FR 47199) for information on how we blended relative weights based on the CMS DRGs and MS–DRGs.

As we implemented cost-based relative weights, some public commenters raised concerns about potential bias in the weights due to "charge compression," which is the practice of applying a higher percentage charge markup over costs to lower cost items and services, and a lower percentage charge markup over costs to higher cost items and services. As a result, the cost-based weights would undervalue high-cost items and overvalue low-cost items if a single cost-to-charge ratio (CCR) is applied to items of widely varying costs in the same cost center. To address this concern, in August 2006, we awarded a contract to the Research Triangle Institute, International (RTI) to study the effects of charge compression in calculating the relative weights and to consider methods to reduce the variation in the CCRs across services within cost centers. For a detailed summary of RTI's findings, recommendations, and public comments that we received on the report, we refer readers to the FY 2009 IPPS/LTCH PPS final rule (73 FR 48452 through 48453). In addition, we refer readers to RTI's July 2008 final report titled "Refining Cost to Charge Ratios for Calculating APC and MS–DRG Relative Payment Weights" (*http://www.rti.org/reports/cms/HHSM-500-2005-0029I/PDF/Refining_Cost_to_Charge_Ratios_200807_Final.pdf*).

In the FY 2009 IPPS final rule (73 FR 48458 through 48467), in response to the RTI's recommendations concerning cost report refinements, we discussed our decision to pursue changes to the cost report to split the cost center for Medical Supplies Charged to Patients into one line for "Medical Supplies Charged to Patients" and another line for "Implantable Devices Charged to Patients." We acknowledged, as RTI had found, that charge compression occurs in several cost centers that exist on the Medicare cost report. However, as we stated in the FY 2009 IPPS final rule, we focused on the CCR for Medical Supplies and Equipment because RTI found that the largest impact on the MS–DRG relative weights could result from correcting charge compression for devices and implants. In determining the items that should be reported in these respective cost centers, we adopted the commenters' recommendations that hospitals use revenue codes established by the AHA's National Uniform Billing Committee to determine the items that should be reported in the "Medical Supplies Charged to Patients" and the "Implantable Devices Charged to Patients" cost centers. Accordingly, a new subscripted line for "Implantable Devices Charged to Patients" was created in July 2009. This new subscripted cost center has been available for use for cost reporting periods beginning on or after May 1, 2009.

As we discussed in the FY 2009 IPPS final rule (73 FR 48458) and in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68519 through 68527), in addition to the findings regarding implantable devices, RTI found that the costs and charges of computed tomography (CT) scans, magnetic resonance imaging (MRI), and cardiac catheterization differ significantly from the costs and charges of other services included in the standard associated cost center. RTI also concluded that both the IPPS and the

OPPS relative weights would better estimate the costs of those services if CMS were to add standard cost centers for CT scans, MRIs, and cardiac catheterization in order for hospitals to report separately the costs and charges for those services and in order for CMS to calculate unique CCRs to estimate the costs from charges on claims data. In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080), we finalized our proposal to create standard cost centers for CT scans, MRIs, and cardiac catheterization, and to require that hospitals report the costs and charges for these services under new cost centers on the revised Medicare cost report Form CMS–2552–10. (We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50075 through 50080) for a detailed discussion of the reasons for the creation of standard cost centers for CT scans, MRIs, and cardiac catheterization.) The new standard cost centers for CT scans, MRIs, and cardiac catheterization are effective for cost reporting periods beginning on or after May 1, 2010, on the revised cost report Form CMS–2552–10.

In the FY 2009 IPPS final rule (73 FR 48468), we stated that, due to what is typically a 3-year lag between the reporting of cost report data and the availability for use in ratesetting, we anticipated that we might be able to use data from the new "Implantable Devices Charged to Patients" cost center to develop a CCR for "Implantable Devices Charged to Patients" in the FY 2012 or FY 2013 IPPS rulemaking cycle. However, as noted in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43782), due to delays in the issuance of the revised cost report Form CMS 2552–10, we determined that a new CCR for "Implantable Devices Charged to Patients" might not be available before FY 2013. Similarly, when we finalized the decision in the FY 2011 IPPS/LTCH PPS final rule to add new cost centers for CT scans, MRIs, and cardiac catheterization, we explained that data from any new cost centers that may be created will not be available until at least 3 years after they are first used (75 FR 50077). In preparation for the FY 2012 IPPS/LTCH PPS rulemaking, we checked the availability of data in the "Implantable Devices Charged to Patients" cost center on the FY 2009 cost reports, but we did not believe that there was a sufficient amount of data from which to generate a meaningful analysis in this particular situation. Therefore, we did not propose to use data from the "Implantable Devices Charged to Patients" cost center to create a distinct CCR for "Implantable Devices Charged to Patients" for use in calculating the MS–DRG relative weights for FY 2012. We indicated that we would reassess the availability of data for the "Implantable Devices Charged to Patients" cost center for the FY 2013 IPPS/LTCH PPS rulemaking cycle and, if appropriate, we would propose to create a distinct CCR at that time.

During the development of the FY 2013 IPPS/LTCH PPS proposed and final rules, hospitals were still in the process of transitioning from the previous cost report Form CMS–2552–96 to the new cost report Form CMS–2552–10. Therefore, we were able to access only those cost reports in the FY 2010 HCRIS with fiscal year begin dates on or after October 1, 2009, and before May 1, 2010; that is, those cost reports on Form CMS–2552–96. Data from the Form CMS–2552–10 cost reports were not available because cost reports filed on the Form CMS–2552–10 were not accessible in the HCRIS. Further complicating matters was that, due to additional unforeseen technical difficulties, the corresponding information regarding charges for implantable devices on hospital claims was not yet available to us in the MedPAR file. Without the breakout in the MedPAR file of charges associated with implantable devices to correspond to the costs of implantable devices on the cost report, we believed that we had no choice but to continue computing the relative weights with the current CCR that combines the costs and charges for supplies and implantable devices. We stated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53281 through 53283) that when we do have the necessary data for supplies and implantable devices on the claims in the MedPAR file to create distinct CCRs for the respective cost centers for supplies and implantable devices, we hoped that we would also have data for an analysis of creating distinct CCRs for CT scans, MRIs, and cardiac catheterization, which could then be finalized through rulemaking. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53281), we stated that, prior to proposing to create these CCRs, we would first thoroughly analyze and determine the impacts of the data, and that distinct CCRs for these new cost centers would be used in the calculation of the relative weights only if they were first finalized through rulemaking.

At the time of the development of the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27506 through 27507), we had a substantial number of hospitals completing all, or some, of these new cost centers on the FY 2011 Medicare cost reports, compared to prior years. We stated that we believed that the analytic findings described using the FY 2011 cost report data and FY 2012 claims data supported our original decision to break out and create new cost centers for implantable devices, MRIs, CT scans, and cardiac catheterization, and we saw no reason to further delay proposing to implement the CCRs of each of these cost centers. Therefore, beginning in FY 2014, we proposed a policy to calculate the MS–DRG relative weights using 19 CCRs, creating distinct CCRs from cost report data for implantable devices, MRIs, CT scans, and cardiac catheterization.

We refer readers to the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27507 through 27509) and final rule (78 FR 50518 through 50523) in which we presented data analyses using distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization. The FY 2014 IPPS/LTCH PPS final rule also set forth our responses to public comments we received on our proposal to implement these CCRs. As explained in more detail in the FY 2014 IPPS/LTCH PPS final rule, we finalized our proposal to use 19 CCRs to calculate MS–DRG relative weights beginning in FY 2014—the then existing 15 cost centers and the 4 new CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization. Therefore, beginning in FY 2014, we calculate the IPPS MS–DRG relative weights using 19 CCRs, creating distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization.

2. Discussion of Policy for FY 2017

Consistent with our established policy, we calculated the proposed MS–DRG relative weights for FY 2017 using two data sources: The MedPAR file as the claims data source and the HCRIS as the cost report data source. We adjusted the charges from the claims to costs by applying the 19 national average CCRs developed from the cost reports. The description of the calculation of the proposed 19 CCRs and the proposed MS–DRG relative weights for FY 2017 is included in section II.G. of the preamble of this proposed rule. As we did with the FY 2016 IPPS/LTCH PPS final rule, we are providing the version of the HCRIS from which we calculated these proposed 19 CCRs on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* Click on the link on the left side of the screen titled, "FY 2017 IPPS Proposed Rule Home Page" or "Acute Inpatient Files for Download."

F. Proposed Changes to Specific MS–DRG Classifications

1. Discussion of Changes to Coding System and Basis for MS–DRG Updates

a. Conversion of MS–DRGs to the International Classification of Diseases, 10th Revision (ICD–10)

As of October 1, 2015, providers use the International Classification of Diseases, 10th Revision (ICD–10) coding system to report diagnoses and procedures for Medicare hospital inpatient services under the MS–DRG system instead of the ICD–9–CM coding system, which was used through September 30, 2015. The ICD–10 coding system includes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, as well as the Official ICD–10–CM and ICD–10–PCS Guidelines for Coding and Reporting. The ICD–10 coding system was initially adopted for transactions conducted on or after October 1, 2013, as described in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Administrative Simplification: Modifications to Medical Data Code Set Standards to Adopt ICD–10–CM and ICD–10–PCS Final Rule published in the **Federal Register** on January 16, 2009 (74 FR 3328 through 3362) (hereinafter referred to as the "ICD–10–CM and ICD–10–PCS final rule"). However, the Secretary of Health and Human Services (the Secretary) issued a final rule that delayed the compliance date for ICD–10 from October 1, 2013, to October 1, 2014. That final rule, entitled "Administrative Simplification: Adoption of a Standard for a Unique Health Plan Identifier; Addition to the National Provider Identifier Requirements; and a Change to the Compliance Date for ICD–10–CM and ICD–10–PCS Medical Data Code Sets," CMS–0040–F, was published in the **Federal Register** on September 5, 2012 (77 FR 54664) and is available for viewing on the Internet at: *http://www.gpo.gov/fdsys/pkg/FR-2012-09-05/pdf/2012-21238.pdf.* On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted, which specified that the Secretary may not adopt ICD–10 prior to October 1, 2015. Accordingly, the U.S. Department of Health and Human Services released a final rule in the **Federal Register** on August 4, 2014 (79 FR 45128 through 45134) that included a new compliance date that required the use of ICD–10 beginning October 1, 2015. The rule also required HIPAA-covered entities to continue to use ICD–9–CM through September 30, 2015.

The anticipated move to ICD–10 necessitated the development of an ICD–10–CM/ICD–10–PCS version of the MS–DRGs. CMS began a project to convert the ICD–9–CM-based MS–DRGs to ICD–10 MS–DRGs. In response to the FY 2011 IPPS/LTCH PPS proposed rule, we received public comments on the creation of the ICD–10 version of the MS–DRGs to be implemented at the same time as ICD–10 (75 FR 50127 and 50128). While we did not propose an ICD–10 version of the MS–DRGs in the FY 2011 IPPS/LTCH PPS proposed rule, we noted that we have been actively involved in converting current MS–DRGs from ICD–9–CM codes to ICD–10 codes and sharing this information through the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee. We undertook this early conversion project to assist other payers and providers in understanding how to implement their own conversion projects. We posted ICD–10 MS–DRGs based on Version 26.0 (FY 2009) of the MS–DRGs. We also posted a paper that describes how CMS went about completing this project and suggestions for other payers and providers to follow. Information on the ICD–10 MS–DRG conversion project can be found on the ICD–10 MS–DRG Conversion Project Web site at: *http://cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html.* We have continued to keep the public updated on our maintenance efforts for ICD–10–CM and ICD–10–PCS coding systems, as well as the General Equivalence Mappings that assist in conversion through the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee. Information on these committee meetings can be found on the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html.*

During FY 2011, we developed and posted Version 28.0 of the ICD–10 MS–DRGs based on the FY 2011 MS–DRGs (Version 28.0) that we finalized in the FY 2011 IPPS/LTCH PPS final rule on the CMS Web site. This ICD–10 MS–DRGs Version 28.0 also included the CC Exclusion List and the ICD–10 version of the hospital-acquired conditions (HACs), which was not posted with Version 26. We also discussed this update at the September 15–16, 2010 and the March 9–10, 2011 meetings of the ICD–9–CM Coordination and Maintenance Committee. The minutes of these two meetings are posted on the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html.*

We reviewed comments on the ICD–10 MS–DRGs Version 28 and made updates as a result of these comments. We called the updated version the ICD–10 MS–DRGs Version 28–R1. We posted a Definitions Manual of ICD–10 MS–DRGs Version 28–R1 on our ICD–10 MS–DRG Conversion Project Web site. To make the review of Version 28–R1 updates easier for the public, we also made available pilot software on a CD ROM that could be ordered through the National Technical Information Service (NTIS). A link to the NTIS ordering page was provided on the CMS ICD–10 MS–DRGs Web site. We stated that we believed that, by providing the ICD–10 MS–DRGs Version 28–R1 Pilot Software (distributed on CD ROM), the public would be able to more easily review and provide feedback on updates to the ICD–10 MS–DRGs. We discussed the updated ICD–10 MS–DRGs Version 28–R1 at the September 14, 2011 ICD–9–CM Coordination and Maintenance Committee meeting. We encouraged the public to continue to review and provide comments on the ICD–10 MS–DRGs so that CMS could continue to update the system.

In FY 2012, we prepared the ICD–10 MS–DRGs Version 29, based on the FY 2012 MS–DRGs (Version 29.0) that we finalized in the FY 2012 IPPS/LTCH PPS final rule. We posted a Definitions Manual of ICD–10 MS–DRGs Version 29 on our ICD–10 MS–DRG Conversion Project Web site. We also prepared a document that describes changes made from Version 28 to Version 29 to facilitate a review. The ICD–10 MS–DRGs Version 29 was discussed at the ICD–9–CM Coordination and Maintenance Committee meeting on March 5, 2012. Information was provided on the types of updates made. Once again the public was encouraged to review and comment on the most recent update to the ICD–10 MS–DRGs.

CMS prepared the ICD–10 MS–DRGs Version 30 based on the FY 2013 MS–DRGs (Version 30) that we finalized in the FY 2013 IPPS/LTCH PPS final rule. We posted a Definitions Manual of the ICD–10 MS–DRGs Version 30 on our ICD–10 MS–DRG Conversion Project Web site. We also prepared a document that describes changes made from Version 29 to Version 30 to facilitate a review. We produced mainframe and computer software for Version 30, which was made available to the public in February 2013. Information on ordering the mainframe and computer software through NTIS was posted on the ICD–10 MS–DRG Conversion Project

Web site. The ICD–10 MS–DRGs Version 30.0 computer software facilitated additional review of the ICD–10 MS–DRGs conversion.

We provided information on a study conducted on the impact of converting the MS–DRGs to ICD–10. Information on this study is summarized in a paper entitled "Impact of the Transition to ICD–10 on Medicare Inpatient Hospital Payments." This paper was posted on the CMS ICD–10 MS–DRGs Conversion Project Web site and was distributed and discussed at the September 15, 2010 ICD–9–CM Coordination and Maintenance Committee meeting. The paper described CMS' approach to the conversion of the MS–DRGs from ICD–9–CM codes to ICD–10 codes. The study was undertaken using the ICD–9–CM MS–DRGs Version 27.0 (FY 2010), which was converted to the ICD–10 MS–DRGs Version 27.0. The study estimated the impact on aggregate payment to hospitals and the distribution of payments across hospitals. The impact of the conversion from ICD–9–CM to ICD–10 on Medicare MS–DRG hospital payments was estimated using FY 2009 Medicare claims data. The study found a hospital payment increase of 0.05 percent using the ICD–10 MS–DRGs Version 27.

CMS provided an overview of this hospital payment impact study at the March 5, 2012 ICD–9–CM Coordination and Maintenance Committee meeting. This presentation followed presentations on the creation of ICD–10 MS–DRGs Version 29.0. A summary report of this meeting can be found on the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html*. At this March 2012 meeting, CMS announced that it would produce an update on this impact study based on an updated version of the ICD–10 MS–DRGs. This update of the impact study was presented at the March 5, 2013 ICD–9–CM Coordination and Maintenance Committee meeting. The study found that moving from an ICD–9–CM-based system to an ICD–10 MS–DRG replicated system would lead to DRG reassignments on only 1 percent of the 10 million MedPAR sample records used in the study. Ninety-nine percent of the records did not shift to another MS–DRG when using an ICD–10 MS–DRG system. For the 1 percent of the records that shifted, 45 percent of the shifts were to a higher-weighted MS–DRG, while 55 percent of the shifts were to lower-weighted MS–DRGs. The net impact across all MS–DRGs was a reduction by 4/10000 or minus 4 pennies per $100. The updated paper is posted on the CMS Web site at: *http://cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html* under the "Downloads" section. Information on the March 5, 2013 ICD–9–CM Coordination and Maintenance Committee meeting can be found on the CMS Web site at: *http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials.html*. This update of the impact paper and the ICD–10 MS–DRG Version 30 software provided additional information to the public who were evaluating the conversion of the MS–DRGs to ICD–10 MS–DRGs.

CMS prepared the ICD–10 MS–DRGs Version 31 based on the FY 2014 MS–DRGs (Version 31) that we finalized in the FY 2014 IPPS/LTCH PPS final rule. In November 2013, we posted a Definitions Manual of the ICD–10 MS–DRGs Version 31 on the ICD–10 MS–DRG Conversion Project Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*. We also prepared a document that described changes made from Version 30 to Version 31 to facilitate a review. We produced mainframe and computer software for Version 31, which was made available to the public in December 2013. Information on ordering the mainframe and computer software through NTIS was posted on the CMS Web site at: *http://cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html* under the "Related Links" section. This ICD–10 MS–DRGs Version 31.0 computer software facilitated additional review of the ICD–10 MS–DRGs conversion. We encouraged the public to submit to CMS any comments on areas where they believed the ICD–10 MS–DRGs did not accurately reflect grouping logic found in the ICD–9–CM MS–DRGs Version 31.

We reviewed public comments received and developed an update of ICD–10 MS–DRGs Version 31, which we called ICD–10 MS–DRGs Version 31–R. We posted a Definitions Manual of the ICD–10 MS–DRGs Version 31–R on the ICD–10 MS–DRG Conversion Project Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*. We also prepared a document that describes changes made from Version 31 to Version 31–R to facilitate a review. We continued to share ICD–10 MS–DRG conversion activities with the public through this Web site.

CMS prepared the ICD–10 MS–DRGs Version 32 based on the FY 2015 MS–DRGs (Version 32) that we finalized in the FY 2015 IPPS/LTCH PPS final rule. In November 2014, we made available a Definitions Manual of the ICD–10 MS DRGs Version 32 on the ICD–10 MS–DRG Conversion Project Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html*. We also prepared a document that described changes made from Version 31–R to Version 32 to facilitate a review. We produced mainframe and computer software for Version 32, which was made available to the public in January 2015. Information on ordering the mainframe and computer software through NTIS was made available on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html* under the "Related Links" section. This ICD–10 MS–DRGs Version 32 computer software facilitated additional review of the ICD–10 MS–DRGs conversion. We encouraged the public to submit to CMS any comments on areas where they believed the ICD–10 MS–DRGs did not accurately reflect grouping logic found in the ICD–9–CM MS–DRGs Version 32. We discussed five requests from the public to update the ICD–10 MS–DRGs Version 32 to better replicate the ICD–9–CM MS–DRGs in section II.G.3., 4., and 5. of the preamble of the FY 2016 IPPS/LTCH PPS final rule. In the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24351), we proposed to implement the MS–DRG code logic in the ICD–10 MS–DRGs Version 32 along with any finalized updates to the ICD–10 MS–DRGs Version 32 for the final ICD–10 MS–DRGs Version 33. In the proposed rule, we proposed the ICD–10 MS–DRGs Version 33 as the replacement logic for the ICD–9–CM based MS–DRGs Version 32 as part of the proposed MS–DRG updates for FY 2016. We invited public comments on how well the ICD–10 MS–DRGs Version 32 replicated the logic of the MS–DRGs Version 32 based on ICD–9–CM codes.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49356 through 49357 and 49363 through 49407), we addressed the public comments we received on the replication in the ICD–10 MS–DRGs Version 32 of the logic of the MS–DRGs Version 32 based on ICD–9–CM codes. We refer readers to that final rule for a discussion of the changes we made in response to public comments.

b. Basis for Proposed FY 2017 MS–DRG Updates

CMS encourages input from our stakeholders concerning the annual IPPS updates when that input is made available to us by December 7 of the year prior to the next annual proposed rule update. For example, to be considered for any updates or changes in FY 2017, comments and suggestions should have been submitted by December 7, 2015. The comments that were submitted in a timely manner for FY 2017 are discussed in this section of the proposed rule. Interested parties should submit any comments and suggestions for FY 2018 by December 7, 2016, via the new CMS MS–DRG Classification Change Requests Mailbox located at: *MSDRGClassificationChange@cms.hhs.gov.*

Following are the changes we are proposing to the MS–DRGs for FY 2017. We are inviting public comment on each of the MS–DRG classification proposed changes described in this rule, as well as our proposals to maintain certain existing MS–DRG classifications, which are also discussed later in this section of the proposed rule. In some cases, we are proposing changes to the MS–DRG classifications based on our analysis of claims data. In other cases, we are proposing to maintain the existing MS–DRG classification based on our analysis of claims data. For this FY 2017 proposed rule, our MS–DRG analysis is based on claims data from the December 2015 update of the FY 2015 MedPAR file, which contains hospital bills received through September 30, 2015, for discharges occurring through September 30, 2015. In our discussion of the proposed MS–DRG reclassification changes that follows, we refer to our analysis of claims data from the "December 2015 update of the FY 2015 MedPAR file."

As explained in previous rulemaking (76 FR 51487), in deciding whether to propose to make further modification to the MS–DRGs for particular circumstances brought to our attention, we consider whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients in the MS–DRG. We evaluate patient care costs using average costs and lengths of stay and rely on the judgment of our clinical advisors to decide whether patients are clinically distinct or similar to other patients in the MS–DRG. In evaluating resource costs, we consider both the absolute and percentage differences in average costs between the cases we select for review and the remainder of cases in the MS–DRG. We also consider variation in costs within these groups; that is, whether observed average differences are consistent across patients or attributable to cases that are extreme in terms of costs or length of stay, or both. Further, we consider the number of patients who will have a given set of characteristics and generally prefer not to create a new MS–DRG unless it would include a substantial number of cases.

In our examination of the claims data, we apply the following criteria established in FY 2008 (72 FR 47169) to determine if the creation of a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS–DRG is warranted:

- A reduction in variance of costs of at least 3 percent.
- At least 5 percent of the patients in the MS–DRG fall within the CC or MCC subgroup.
- At least 500 cases are in the CC or MCC subgroup.
- There is at least a 20-percent difference in average costs between subgroups.
- There is a $2,000 difference in average costs between subgroups.

In order to warrant creation of a CC or MCC subgroup within a base MS–DRG, the subgroup must meet all five of the criteria.

We note that some of the issues being evaluated for the FY 2017 MS–DRGs update continue to relate to the need for the ICD–10 MS–DRGs to accurately replicate the logic of the ICD–9–CM based version of the MS–DRGs. Replication is important because both the logic for the proposed MS–DRGs and the data source used to calculate and develop proposed relative payment weights are based on the same MedPAR claims data. In other words, as the logic for the proposed FY 2017 ICD–10 MS–DRGs is based upon the FY 2015 ICD–9–CM MedPAR claims data, the data source used to calculate and develop the proposed FY 2017 relative payment weights is also based on the FY 2015 ICD–9–CM MedPAR claims data, including any proposed MS–DRG classification changes discussed in this proposed rule. This is consistent with how the current FY 2016 relative payment weights are based on the ICD–9–CM diagnosis and procedure codes from the FY 2014 MedPAR claims data that were grouped through the ICD–9–CM version of the FY 2016 GROUPER Version 33. We note that we made the MS–DRG GROUPER and Medicare Code Editor (MCE) ICD–9–CM Software Version 33 available to the public for use in analyzing ICD–9–CM data to create relative payment weights using ICD–9–CM data on our CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page.html?DLSort=0&DLEntries=10&DLPage=1&DLSortDir=ascending.* Therefore, as discussed in section II.G. of the preamble of this proposed rule, ICD–9–CM data were used for computing the proposed FY 2017 MS–DRG relative payment weights. If the ICD–9 and ICD–10 versions of MS–DRGs cease to be replications of each other, the relative payment weights computed using the ICD–9 claims data and MS–DRGs would be inconsistent with the relative payment weights assigned for the ICD–10 MS–DRGs, causing unintended payment redistributions. Thus, if the findings of our data analyses and the recommendations of our clinical advisors supported modifications to the current ICD–10 MS–DRG structure, prior to proposing any changes, we first evaluated whether the requested change could be replicated in the ICD–9–CM MS–DRGs. If the answer was "yes," from a replication perspective, the change was considered feasible. If the answer was "no," we examined whether the change in the ICD–10 MS–DRGs was likely to cause a significant number of patient cases to change or "shift" ICD–10 MS–DRGs. If relatively few patient cases would be impacted, we evaluated if it would be feasible to propose the change even though it could not be replicated by the ICD–9 MS–DRGs because it would not cause a material payment redistribution. For the ICD–10 MS–DRG classification change requests that could not be replicated in ICD–9–CM and that would cause a significant number of patient cases to shift MS–DRG assignment, we considered other alternatives.

2. Pre-Major Diagnostic Category (Pre-MDC): Total Artificial Heart Replacement

An ICD–10 MS–DRG replication issue regarding the assignment of two ICD–10–PCS procedure codes was identified after the October 1, 2015 implementation of the Version 33 ICD–10 MS–DRGs. ICD–10–PCS procedure codes 02RK0JZ (Replacement of right ventricle with synthetic substitute, open approach) and 02RL0JZ (Replacement of left ventricle with synthetic substitute, open approach), when reported together, describe a biventricular heart replacement (artificial heart). Under the Version 32 ICD–9–CM based MS–DRGs, this procedure was described by ICD–9–CM procedure code 37.52 (Implantation of total internal biventricular heart replacement system) and grouped to MS–DRGs 001 and 002 (Heart Transplant or Implant of Heart Assist System with and without MCC, respectively).

As discussed in section II.F.1.a. of the preamble of this proposed rule, to assist in the conversion from the ICD–9–CM based MS–DRGs to ICD–10, beginning in FY 2011, draft versions of the ICD–10 based MS–DRGs were developed and made available for public comment. The two ICD–10–PCS procedure codes (02RK0JZ and 02RL0JZ) were assigned as a "cluster" to the draft ICD–10 based MS–DRGs 001 and 002 in prior draft versions of the ICD–10 MS–DRGs. In ICD–10–PCS, a cluster is the term used to describe when a combination of ICD–10–PCS procedure codes are needed to fully satisfy the equivalent meaning of an ICD–9–CM procedure code for it to be considered a plausible translation. Upon review of prior draft versions of the ICD–10 MS–DRGs, it was determined that Version 30 was the last version to include ICD–10–PCS procedure codes 02RK0JZ and 02RL0JZ as a code cluster (from ICD–9–CM procedure code 37.52) that grouped to the draft ICD–10 based MS–DRGs 001 and 002. Subsequent draft versions of the ICD–10 MS–DRGs inadvertently omitted this code cluster from those MS–DRGs.

Therefore, for FY 2017, we are proposing to assign ICD–10–PCS procedure codes 02RK0JZ and 02RL0JZ as a code cluster to ICD–10 Version 34 MS–DRGs 001 and 002 (Heart Transplant or Implant of Heart Assist System with and without MCC, respectively) to accurately replicate the Version 32 ICD–9–CM based MS–DRG logic of procedure code 37.52. We are inviting public comments on our proposal.

3. MDC 1 (Diseases and Disorders of the Nervous System)

a. Endovascular Embolization (Coiling) or Occlusion of Head and Neck Procedures

We received a repeat request to change the MS–DRG assignment for procedure codes describing endovascular embolization (coiling) or occlusion of the head and neck. This topic was discussed in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28005 through 28007); the FY 2015 IPPS/LTCH PPS final rule (79 FR 49883 through 49886); the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24351 through 24356); and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49358 through 49363). For these 2 fiscal years, we did not change the MS–DRG assignment for procedure codes describing endovascular embolization (coiling) or occlusion of the head and neck for the reasons discussed in these proposed and final rules.

For FY 2017, the requestor again asked that CMS change the MS–DRG assignment for procedure codes describing endovascular embolization or occlusion of the head and neck as well as several other codes describing endovascular procedures of the head and neck.

The ICD–10–PCS procedure codes listed in the following table capture endovascular embolization or occlusion of the head and neck procedures that are assigned to the following MS–DRGs in ICD–10 Version 33 MS–DRGs: MS–DRG 020 (Intracranial Vascular Procedures with Principal Diagnosis of Hemorrhage with MCC); MS–DRG 021 (Intracranial Vascular Procedures with Principal Diagnosis of Hemorrhage with CC); MS–DRG 022 (Intracranial Vascular Procedures with Principal Diagnosis of Hemorrhage without CC/MCC); MS–DRG 023 (Craniotomy with Major Device Implant/Acute Complex CNS Principal Diagnosis with MCC or Chemo Implant); MS–DRG 024 (Craniotomy with Major Device Implant/Acute Complex CNS Principal Diagnosis without MCC); MS–DRG 025 (Craniotomy and Endovascular Intracranial Procedures with MCC); MS–DRG 026 (Craniotomy and Endovascular Intracranial Procedures with CC); and MS–DRG 027 (Craniotomy and Endovascular Intracranial Procedures without CC/MCC):

ICD–10–PCS CODES FOR ENDOVASCULAR EMBOLIZATION OR OCCLUSION OF THE HEAD AND NECK PROCEDURES ASSIGNED TO MS–DRGS 020 THROUGH 027 IN ICD–10 MS–DRGS VERSION 33

ICD–10–PCS code	Code description
03LG3BZ	Occlusion of intracranial artery with bioactive intraluminal device, percutaneous approach.
03LG3DZ	Occlusion of intracranial artery with intraluminal device, percutaneous approach.
03LG4BZ	Occlusion of intracranial artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LG4DZ	Occlusion of intracranial artery with intraluminal device, percutaneous endoscopic approach.
03LH3BZ	Occlusion of right common carotid artery with bioactive intraluminal device, percutaneous approach.
03LH3DZ	Occlusion of right common carotid artery with intraluminal device, percutaneous approach.
03LH4BZ	Occlusion of right common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LH4DZ	Occlusion of right common carotid artery with intraluminal device, percutaneous endoscopic approach.
03LJ3BZ	Occlusion of left common carotid artery with bioactive intraluminal device, percutaneous approach.
03LJ3DZ	Occlusion of left common carotid artery with intraluminal device, percutaneous approach.
03LJ4BZ	Occlusion of left common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LJ4DZ	Occlusion of left common carotid artery with intraluminal device, percutaneous endoscopic approach.
03LK3BZ	Occlusion of right internal carotid artery with bioactive intraluminal device, percutaneous approach.
03LK3DZ	Occlusion of right internal carotid artery with intraluminal device, percutaneous approach.
03LK4BZ	Occlusion of right internal carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LK4DZ	Occlusion of right internal carotid artery with intraluminal device, percutaneous endoscopic approach.
03LL3BZ	Occlusion of left internal carotid artery with bioactive intraluminal device, percutaneous approach.
03LL3DZ	Occlusion of left internal carotid artery with intraluminal device, percutaneous approach.
03LL4BZ	Occlusion of left internal carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LL4DZ	Occlusion of left internal carotid artery with intraluminal device, percutaneous endoscopic approach.
03LM3BZ	Occlusion of right external carotid artery with bioactive intraluminal device, percutaneous approach.
03LM3DZ	Occlusion of right external carotid artery with intraluminal device, percutaneous approach.
03LM4BZ	Occlusion of right external carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LM4DZ	Occlusion of right external carotid artery with intraluminal device, percutaneous endoscopic approach.
03LN3BZ	Occlusion of left external carotid artery with bioactive intraluminal device, percutaneous approach.
03LN3DZ	Occlusion of left external carotid artery with intraluminal device, percutaneous approach.
03LN4BZ	Occlusion of left external carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LN4DZ	Occlusion of left external carotid artery with intraluminal device, percutaneous endoscopic approach.
03LP3BZ	Occlusion of right vertebral artery with bioactive intraluminal device, percutaneous approach.
03LP3DZ	Occlusion of right vertebral artery with intraluminal device, percutaneous approach.
03LP4BZ	Occlusion of right vertebral artery with bioactive intraluminal device, percutaneous endoscopic approach.

ICD–10–PCS Codes for Endovascular Embolization or Occlusion of the Head and Neck Procedures Assigned to MS–DRGs 020 Through 027 in ICD–10 MS–DRGs Version 33—Continued

ICD–10–PCS code	Code description
03LP4DZ	Occlusion of right vertebral artery with intraluminal device, percutaneous endoscopic approach.
03LQ3BZ	Occlusion of left vertebral artery with bioactive intraluminal device, percutaneous approach.
03LQ3DZ	Occlusion of left vertebral artery with intraluminal device, percutaneous approach.
03LQ4BZ	Occlusion of left vertebral artery with bioactive intraluminal device, percutaneous endoscopic approach.
03LQ4DZ	Occlusion of left vertebral artery with intraluminal device, percutaneous endoscopic approach.
03LR3DZ	Occlusion of face artery with intraluminal device, percutaneous approach.
03LR4DZ	Occlusion of face artery with intraluminal device, percutaneous endoscopic approach.
03LS3DZ	Occlusion of right temporal artery with intraluminal device, percutaneous approach.
03LS4DZ	Occlusion of right temporal artery with intraluminal device, percutaneous endoscopic approach.
03LT3DZ	Occlusion of left temporal artery with intraluminal device, percutaneous approach.
03LT4DZ	Occlusion of left temporal artery with intraluminal device, percutaneous endoscopic approach.
03VG3BZ	Restriction of intracranial artery with bioactive intraluminal device, percutaneous approach.
03VG3DZ	Restriction of intracranial artery with intraluminal device, percutaneous approach.
03VG4BZ	Restriction of intracranial artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VG4DZ	Restriction of intracranial artery with intraluminal device, percutaneous endoscopic approach.
03VH3BZ	Restriction of right common carotid artery with bioactive intraluminal device, percutaneous approach.
03VH3DZ	Restriction of right common carotid artery with intraluminal device, percutaneous approach.
03VH4BZ	Restriction of right common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VH4DZ	Restriction of right common carotid artery with intraluminal device, percutaneous endoscopic approach.
03VJ3BZ	Restriction of left common carotid artery with bioactive intraluminal device, percutaneous approach.
03VJ3DZ	Restriction of left common carotid artery with intraluminal device, percutaneous approach.
03VJ4BZ	Restriction of left common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VJ4DZ	Restriction of left common carotid artery with intraluminal device, percutaneous endoscopic approach.
03VK3BZ	Restriction of right internal carotid artery with bioactive intraluminal device, percutaneous approach.
03VK3DZ	Restriction of right internal carotid artery with intraluminal device, percutaneous approach.
03VK4BZ	Restriction of right internal carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VK4DZ	Restriction of right internal carotid artery with intraluminal device, percutaneous endoscopic approach.
03VL3BZ	Restriction of left internal carotid artery with bioactive intraluminal device, percutaneous approach.
03VL3DZ	Restriction of left internal carotid artery with intraluminal device, percutaneous approach.
03VL4BZ	Restriction of left internal carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VL4DZ	Restriction of left internal carotid artery with intraluminal device, percutaneous endoscopic approach.
03VM3BZ	Restriction of right external carotid artery with bioactive intraluminal device, percutaneous approach.
03VM3DZ	Restriction of right external carotid artery with intraluminal device, percutaneous approach.
03VM4BZ	Restriction of right external carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VM4DZ	Restriction of right external carotid artery with intraluminal device, percutaneous endoscopic approach.
03VN3BZ	Restriction of left external carotid artery with bioactive intraluminal device, percutaneous approach.
03VN3DZ	Restriction of left external carotid artery with intraluminal device, percutaneous approach.
03VN4BZ	Restriction of left external carotid artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VN4DZ	Restriction of left external carotid artery with intraluminal device, percutaneous endoscopic approach.
03VP3BZ	Restriction of right vertebral artery with bioactive intraluminal device, percutaneous approach.
03VP3DZ	Restriction of right vertebral artery with intraluminal device, percutaneous approach.
03VP4BZ	Restriction of right vertebral artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VP4DZ	Restriction of right vertebral artery with intraluminal device, percutaneous endoscopic approach.
03VQ3BZ	Restriction of left vertebral artery with bioactive intraluminal device, percutaneous approach.
03VQ3DZ	Restriction of left vertebral artery with intraluminal device, percutaneous approach.
03VQ4BZ	Restriction of left vertebral artery with bioactive intraluminal device, percutaneous endoscopic approach.
03VQ4DZ	Restriction of left vertebral artery with intraluminal device, percutaneous endoscopic approach.
03VR3DZ	Restriction of face artery with intraluminal device, percutaneous approach.
03VR4DZ	Restriction of face artery with intraluminal device, percutaneous endoscopic approach.
03VS3DZ	Restriction of right temporal artery with intraluminal device, percutaneous approach.
03VS4DZ	Restriction of right temporal artery with intraluminal device, percutaneous endoscopic approach.
03VT3DZ	Restriction of left temporal artery with intraluminal device, percutaneous approach.
03VT4DZ	Restriction of left temporal artery with intraluminal device, percutaneous endoscopic approach.
03VU3DZ	Restriction of right thyroid artery with intraluminal device, percutaneous approach.
03VU4DZ	Restriction of right thyroid artery with intraluminal device, percutaneous endoscopic approach.
03VV3DZ	Restriction of left thyroid artery with intraluminal device, percutaneous approach.
03VV4DZ	Restriction of left thyroid artery with intraluminal device, percutaneous endoscopic approach.

Cases reporting any of the ICD–10–PCS procedures codes listed in the table above that are assigned to MS–DRGs 020, 021, and 022 under MDC 1 require a principal diagnosis of hemorrhage. Cases reporting any of the ICD–10–PCS procedure codes listed in the table above that are assigned to MS–DRGs 023 and 024 require the insertion of a major implant or an acute complex central nervous system (CNS) principal diagnosis. Cases reporting any of the ICD–10–PCS procedure codes listed in the table above that are assigned to MS–DRGs 025, 026, and 027 do not have a principal diagnosis of hemorrhage, an acute complex CNS principal diagnosis, or a major device implant.

The requestor expressed concerns about the appropriateness of the MS–DRG assignment for the endovascular embolization or occlusion of head and neck procedures. The requestor stated that past data demonstrated that the cost of cases involving endovascular coils exceeds the average cost of all cases within each of the MS–DRGs to which these procedures are assigned. The requestor pointed out that these procedures were formerly captured by the following ICD–9–CM codes that were assigned to MS–DRGs 020 through 027:

- 39.72 (Endovascular (total) embolization or occlusion of head and neck vessels);
- 39.75 (Endovascular embolization or occlusion of vessel(s) of head or neck using bare coils); and
- 39.76 (Endovascular embolization or occlusion of vessel(s) of head or neck using bioactive coils).

The commenter also expressed concern about the appropriateness of the current ICD–10 MS–DRG assignment of the following ICD–9–CM codes that describe other endovascular procedures of head and neck that were previously assigned to MS–DRGs 023 through 027 in the ICD–9–CM MS–DRGs Version 32. The commenter stated that these procedures are more clinically complex than other procedures assigned to these MS–DRGs.

- 00.62 (Percutaneous angioplasty of intracranial vessels(s));
- 39.74 (Endovascular removal of obstruction from head and neck vessel(s)); and
- 39.79 (Other endovascular procedures on other vessels).

We examined claims data from the December 2015 update of the FY 2015 MedPAR file for the endovascular embolization or occlusion of the head and neck procedures or other endovascular procedures reported under ICD–9–CM procedure codes 00.62, 39.72, 39.74, 39.75, 39.76, and 39.79 in MS–DRGs 020 through 027. The table below shows our findings.

ENDOVASCULAR EMBOLIZATION OR OCCLUSION OF THE HEAD AND NECK PROCEDURES AND OTHER ENDOVASCULAR PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 020—All cases	1,213	16.44	$70,716
MS–DRG 020—Cases with procedure code 00.62, 39.72, 39.74, 39.75, 39.76, or 39.79	895	16.15	72,357
MS–DRG 021—All cases	350	13.74	53,289
MS–DRG 021—Cases with procedure code 00.62, 39.72, 39.74, 39.75, 39.76, or 39.79	272	13.21	53,478
MS–DRG 022—All cases	84	7.83	33,598
MS–DRG 022—Cases with procedure code 00.62, 39.72, 39.74, 39.75, 39.76, or 39.79	63	7.27	33,606
MS–DRG 023—All cases	6,360	10.63	38,204
MS–DRG 023—Cases with procedure code 00.62, 39.72, 39.74, 39.75, 39.76, or 39.79	2,183	8.57	38,935
MS–DRG 024—All cases	2,376	5.52	28,270
MS–DRG 024—Cases with procedure code 00.62, 39.72, 39.74, 39.75, 39.76, or 39.79	1,402	5.46	28,543
MS–DRG 025—All cases	17,756	9.19	29,657
MS–DRG 025—Cases with procedure code 00.62, 39.72, 39.74, 39.75, 39.76 or 39.79	671	9.20	47,579
MS–DRG 026—All cases	7,630	5.80	21,441
MS–DRG 026—Cases with procedure code 00.62, 39.72, 39.74, 39.75, 39.76, or 39.79	825	3.11	27,429
MS–DRG 027—All cases	9,628	2.99	17,158
MS–DRG 027—Cases with procedure code 00.62, 39.72, 39.74, 39.75, 39.76 or 39.79	1,847	1.62	22,845

As can be seen from the table, most of the cases of endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures reported with procedure codes 00.62, 39.72, 39.74, 39.75, 39.76, and 39.79 occur in MS–DRGs 023, 024, and 027. There were 2,183 of these procedure cases reported in MS–DRG 023 with an average length of stay of 8.57 days and average costs of $38,935, compared to an average length of stay of 10.63 days and average costs of $38, 204 for all 6,360 cases reported in MS–DRG 023. There were 1,402 of these cases reported in MS–DRG 024 with an average length of stay of 5.46 days and average costs of $28,543, compared to an average length of stay of 5.52 days and average costs of $28,270 for all 2,376 cases reported in MS–DRG 024. There were 1,847 of these cases reported in MS–DRG 027 with an average length of stay of 1.62 days and average costs of $22,845, compared to an average length of stay of 2.99 days and average costs of $17,158 for all 9,628 cases reported in MS–DRG 027. The average costs for endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures cases reported in MS–DRGs 023 and 024 are not significantly different from the average costs for all cases reported in MS–DRGs 023 and 024. The average costs for endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures cases reported in MS–DRG 027 are higher ($22,845) than the average costs of all cases reported in MS–DRG 027 ($17,158). However, average costs are not significantly different for the endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures cases reported in MS–DRG 020 ($72,357) compared to the average costs for all cases ($70,716) reported in MS–DRS 020; for the endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures cases reported in MS–DRG 021 ($53,478) compared to the average costs for all cases ($53,289) reported in MS–DRG 021; and for the endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures cases reported in MS–DRG 022 ($33,606) compared to the average costs for all cases ($33,598) reported in MS–DRG 022.

Average costs were higher for the 671 endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures cases reported in MS–DRG 025 ($47,579) compared to the average costs for all 17,756 cases ($29,657) reported in MS–DRG 025. The average costs also were higher for the 825 endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures cases reported in MS–DRG 26 ($27,429) compared to the average costs for all 7,630 cases ($21,441) reported in MS–DRG 26. Given that average costs are similar for most endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures cases reported in MS–DRGs 020, 021, 022, 023, 024, 025, 026, and 027, we do not believe that all endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures should be reassigned from these eight MS–DRGs.

We also examined the average costs for each specific ICD–9–CM code compared to the average costs of all cases within each of the eight MS–DRGs. The following table shows our findings.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 020—All cases	1,213	16.44	$70,716
MS–DRG 020—Cases with code 00.62	11	16.09	95,422
MS–DRG 020—Cases with code 39.72	422	16.31	74,951
MS–DRG 020—Cases with code 39.74	9	16.78	71,478
MS–DRG 020—Cases with code 39.75	424	15.79	69,081
MS–DRG 020—Cases with code 39.76	39	18.26	71,630
MS–DRG 020—Cases with code 39.79	25	16.64	73,043
MS–DRG 021—All cases	350	13.74	53,289
MS–DRG 021—Cases with code 00.62	1	11.00	75,492
MS–DRG 021—Cases with code 39.72	130	13.12	54,715
MS–DRG 021—Cases with code 39.74	1	11.00	75,492
MS–DRG 021—Cases with code 39.75	133	13.46	52,819
MS–DRG 021—Cases with code 39.76	7	10.57	48,749
MS–DRG 021—Cases with code 39.79	3	12.00	40,458
MS–DRG 022—All cases	84	7.83	33,598
MS–DRG 022—Cases with code 00.62	0	0	0
MS–DRG 022—Cases with code 39.72	40	6.43	32,598
MS–DRG 022—Cases with code 39.74	0	0	0
MS–DRG 022—Cases with code 39.75	21	8.81	32,690
MS–DRG 022—Cases with code 39.76	3	10.00	62,417
MS–DRG 022—Cases with code 39.79	0	0	0
MS–DRG 023—All cases	6,360	10.63	38,204
MS–DRG 023—Cases with code 00.62	67	9.30	43,741
MS–DRG 023—Cases with code 39.72	56	11.14	52,589
MS–DRG 023—Cases with code 39.74	2,016	8.30	38,047
MS–DRG 023—Cases with code 39.75	20	12.65	53,837
MS–DRG 023—Cases with code 39.76	3	23.00	84,947
MS–DRG 023—Cases with code 39.79	71	13.08	50,720
MS–DRG 024—All cases	2,376	5.52	28,270
MS–DRG 024—Cases with code 00.62	76	6.74	32,415
MS–DRG 024—Cases with code 39.72	31	6.35	29,977
MS–DRG 024—Cases with code 39.74	1,284	5.35	28,268
MS–DRG 024—Cases with code 39.75	8	6.50	50,333
MS–DRG 024—Cases with code 39.76	2	1.50	19,567
MS–DRG 024—Cases with code 39.79	27	6.74	28,019
MS–DRG 025—All cases	17,756	9.19	29,657
MS–DRG 025—Cases with code 00.62	17	5.88	29,036
MS–DRG 025—Cases with code 39.72	380	9.46	51,082
MS–DRG 025—Cases with code 39.74	55	9.87	45,895
MS–DRG 025—Cases with code 39.75	139	8.94	52,188
MS–DRG 025—Cases with code 39.76	25	5.84	38,654
MS–DRG 025—Cases with code 39.79	82	11.04	39,839
MS–DRG 026—All cases	7,630	5.80	21,441
MS–DRG 026—Cases with code 00.62	31	3.48	25,611
MS–DRG 026—Cases with code 39.72	481	3.00	27,180
MS–DRG 026—Cases with code 39.74	16	4.69	27,519
MS–DRG 026—Cases with code 39.75	253	2.77	26,863
MS–DRG 026—Cases with code 39.76	31	3.32	27,891
MS–DRG 026—Cases with code 39.79	45	5.42	37,410
MS–DRG 027—All cases	9,628	2.99	17,158
MS–DRG 027—Cases with code 00.62	61	2.23	21,337
MS–DRG 027—Cases with code 39.72	1,159	1.58	22,893
MS–DRG 027—Cases with code 39.74	13	1.62	69,081
MS–DRG 027—Cases with code 39.75	580	1.63	23,296
MS–DRG 027—Cases with code 39.76	61	1.74	27,403
MS–DRG 027—Cases with code 39.79	30	1.53	17,740

As can be seen from the table above, there are a large number of cases reporting procedure code 39.74 in MS–DRGs 023 and 024. There were 2,016 cases that reported procedure code 39.74 in MS–DRG 023 compared to 6,360 total cases reported in the MS–DRG. The cases that reported procedure code 39.74 in MS–DRG 023 had an average length of stay of 8.30 days and average costs of $38,047, compared to an average length of stay of 10.63 days and average costs of $38,204 for all cases reported in MS–DRG 023. There were 1,284 cases that reported procedure code 39.74 in MS–DRG 024 compared to 2,376 total cases reported in MS–DRG 024. The cases that reported procedure code 39.74 in MS–DRG 024 had an average length of stay of 5.35 days and average costs of $28,268, compared to an average length of stay of 5.52 days and average costs of $28,270 for all cases reported in MS–DRG 024. The average length of stay and average costs for cases that reported procedure code 39.74 are very similar to the average length of stay and average costs for all cases reported in MS–DRGs 023 and 024. The only other group of endovascular embolization or occlusion of the head and neck procedures and other endovascular procedures cases that exceeded 1,000 in number was reported in MS–DRG 027. There were 1,159 cases that reported procedure code 39.72 in MS–DRG 027, compared to 9,628 total cases reported in MS–DRG 027. The cases that reported procedure code 39.72 in MS–DRG 027 had an average length of stay of 1.58 days and average costs of $22,893, compared to an average length of stay of 2.99 days and average costs of $17,158 for all cases reported in MS–DRG 027. In other words, the cases that reported procedure code 39.72 in MS–DRG 027 had a shorter average length of stay and average costs that were $5,735 higher than the average costs for all cases reported in MS–DRG 027. The cases that reported procedure code 39.72 in MS–DRG 020 had a shorter average length of stay and average costs that were $4,235 higher than the average costs for all cases reported in MS–DRG 020. However, the average costs for the cases that reported procedure code 39.72 in MS–DRGs 021, 022, and 024 were close to the average costs for all cases reported in the three MS–DRGs ($54,715 compared to $53,289 in MS–DRG 021; $32,598 compared to $33,598 in MS–DRG 022; and $29,997 compared to $28,270 in MS–DRG 024).

Our clinical advisors reviewed this issue and advised us that the endovascular embolization or occlusion of head and neck procedures and other endovascular procedures currently are appropriately assigned to MS–DRGs 020 through 027. They did not support reassigning these procedures from MS–DRGs 020 through 027 to another MS–DRG or creating a new MS–DRG for these procedures. Our clinical advisors stated that these procedures are all clinically similar to other procedures in these MS–DRGs. In addition, they stated that the surgical techniques are all designed to correct the same clinical problem and advised us against reassigning the procedures from MS–DRGs 020 through 027.

Based on the findings from our data analyses and the recommendations from our clinical advisors, we are not proposing to reassign the cited endovascular embolization or occlusion of head and neck procedures and other endovascular procedures from MS–DRGs 020 through 027 to another MS–DRG or to create a new MS–DRG for these procedures for FY 2017. We are inviting public comments on our proposal to maintain the current MS–DRG assignments of these procedures in MS–DRGs 020 through 027.

b. Mechanical Complication Codes

We received a request to reassign the following four ICD–10–CM diagnosis codes from MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs) under MS–DRGs 919, 920, and 921 (Complications of Treatment with MCC, with CC, and without CC/MCC, respectively) to MDC 1 (Diseases and Disorders of the Nervous System) under MS–DRGs 091, 092, and 093 (Other Disorders of the Nervous System with MCC, with CC, and without CC/MCC, respectively):

- T85.610A (Breakdown (mechanical) of epidural and subdural infusion catheter, initial encounter);
- T85.620A (Displacement of epidural and subdural infusion catheter, initial encounter);
- T85.630A (Leakage of epidural and subdural infusion catheter, initial encounter); and
- T85.690A (Other mechanical complication of epidural and subdural infusion catheter, initial encounter).

The requestor stated that these ICD–10–CM diagnosis code titles clearly describe mechanical complications of nervous system devices, implants, or grafts and are unquestionably nervous system codes. Therefore, the requestor recommended that these diagnosis codes be reassigned to MDC 1 under MS–DRGs 091, 092, and 093.

We examined ICD–10–CM diagnosis codes T85.610A, T85.620A, T85.630A, and T85.690A that are currently assigned to MDC 21 under MS–DRGs 919, 920, and 921. We note that the predecessor ICD–9–CM diagnosis code for these four ICD–10–CM diagnosis codes was diagnosis code 996.59 (Mechanical complication due to other implant and internal device, not elsewhere classified), which also was assigned to MDC 21 under MS–DRGs 919, 920, and 921. ICD–9–CM diagnosis code 996.59 did not describe the location of the device. However, ICD–10–CM diagnosis codes T85.610A, T85.620A, T85.630A, and T85.690A provide additional detail that describes the location of the mechanical complication as being within the nervous system.

Based on the results of our examination, we agree with the requestor that ICD–10–CM diagnosis codes T85.610A, T85.620A, T85.630A, and T85.690A describe conditions occurring within the nervous system. Within the ICD–9–CM MS–DRGs, codes describing nervous system disorders were assigned to MDC 1. The prior ICD–9–CM codes for mechanical complications did not indicate the type of complication and therefore could not be assigned to a specific MDC. Therefore, the nonspecific complication codes were assigned to MDC 21. These new ICD–10–CM diagnosis codes describe concepts not previously captured by the ICD–9–CM codes and capture nervous system conditions. Therefore, ICD–10–CM diagnosis codes T85.610A, T85.620A, T85.630A, and T85.690A should be reassigned from MDC 21 under MS–DRGs 919, 920, and 921 to MDC 1 under MS–DRGs 091, 092, and 093. Our clinical advisors reviewed this issue and also agree that the four ICD–10–CM diagnosis codes describe conditions occurring within the nervous system and therefore should be reassigned from MDC 21 to MDC 1. Based on the results of our analysis and the recommendations of our clinical advisors, we are proposing to reassign ICD–10–CM diagnosis codes T85.610A, T85.620A, T85.630A, and T85.690A from MDC 21 under MS–DRGs 919, 920, and 921 to MDC 1 under MS–DRGs 091, 092, and 093.

We are inviting public comments on our proposal.

4. MDC 4 (Diseases and Disorders of the Ear, Nose, Mouth and Throat)

a. Proposed Reassignment of Diagnosis Code R22.2 (Localized Swelling, Mass and Lump, Trunk)

We received a request to reassign ICD–10–CM diagnosis code R22.2 (Localized swelling, mass and lump, trunk) from MDC 4 (Diseases and Disorders of the Respiratory System) to MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast). The requestor stated that this code is used to capture a buttock mass. The requestor pointed out that the ICD–10–CM index for localized swelling and localized mass directs the coder to diagnosis code R22.2 for both the chest and the trunk as sites.

We reviewed this issue and note that diagnosis code R22.2 is included in a category of ICD–10–CM codes describing symptoms and signs involving the skin and subcutaneous tissue (categories R20 through R23). Diagnosis code R22.2 is clearly designated within the ICD–10 coding system as a code that describes a condition of the skin and subcutaneous tissue. Therefore, we agree with the requester that ICD–10–CM diagnosis code R22.2 should be reassigned from MDC 4 to MDC 9. One of the predecessor ICD–9–CM codes for ICD–10–CM diagnosis code R22.2 was diagnosis code 782.2 (Localized superficial swelling, mass, or lump), which is assigned to MS–DRG 606 and 607 (Minor Skin Disorders with and without MCC, respectively). Our clinical advisors reviewed this issue and agree that ICD–10–CM diagnosis code R22.2 captures a skin diagnosis. Therefore, for FY 2017, we are proposing to reassign ICD–10–CM diagnosis code R22.2 from MDC 4 to MDC 9 under MS–DRGs 606 and 607 (Minor Skin Disorders with and without MCC, respectively).

We are inviting public comments on our proposal to reassign ICD–10–CM diagnosis code R22.2 from MDC 4 to MDC 9 under MS–DRGs 606 and 607.

b. Pulmonary Embolism With tPA or Other Thrombolytic Therapy

We received a request to create a new MS–DRG or to reassign cases with a principal diagnosis of pulmonary embolism where tPA or other thrombolytic therapy was administered from MS–DRGs 175 and 176 (Pulmonary Embolism with and without MCC, respectively) to a higher paying MS–DRG. The requestor suggested that CMS review cases reporting the following ICD–9–CM diagnosis codes describing pulmonary embolism: 415.11 (Iatrogenic pulmonary embolism and infarction), 415.12 (Septic pulmonary embolism), 415.13 (Saddle embolus of pulmonary artery), and 415.19 (Other pulmonary embolism and infarction), when reported in combination with ICD–9–CM procedure code 99.10 (Injection or infusion of thrombolytic agent), to identify that thrombolytic therapy was administered.

The comparable ICD–10–CM diagnosis code translations for the ICD–9–CM pulmonary embolism diagnosis codes to which the requestor cited consist of the following:

ICD–10–CM diagnosis code	Description
I26.01	Septic pulmonary embolism with acute cor pulmonale.
I26.02	Saddle embolus of pulmonary artery with acute cor pulmonale.
I26.09	Other pulmonary embolism with acute cor pulmonale.
I26.90	Septic pulmonary embolism without acute cor pulmonale.
I26.92	Saddle embolus of pulmonary artery without acute cor pulmonale.
I26.99	Other pulmonary embolism without acute cor pulmonale.

Thrombolytic therapy is identified with the following ICD–10–PCS procedure codes:

ICD–10–PCS procedure code	Description
3E03017	Introduction of other thrombolytic into peripheral vein, open approach.
3E03317	Introduction of other thrombolytic into peripheral vein, percutaneous approach.
3E04017	Introduction of other thrombolytic into central vein, open approach.
3E04317	Introduction of other thrombolytic into central vein, percutaneous approach.
3E05017	Introduction of other thrombolytic into peripheral artery, open approach.
3E05317	Introduction of other thrombolytic into peripheral artery, percutaneous approach.
3E06017	Introduction of other thrombolytic into central artery, open approach.
3E06317	Introduction of other thrombolytic into central artery, percutaneous approach.

A pulmonary embolism is an obstruction of pulmonary vasculature most commonly caused by a venous thrombus, and less commonly by fat or tumor tissue or air bubbles or both. Risk factors for a pulmonary embolism include prolonged immobilization from any cause, obesity, cancer, fractured hip or leg, use of certain medications such as oral contraceptives, presence of certain medical conditions such as heart failure, sickle cell anemia, or certain congenital heart defects. Common symptoms of pulmonary embolism include shortness of breath with or without chest pain, tachycardia, hemoptysis, low grade fever, pleural effusion, and depending on the etiology of the embolus, might include lower extremity pain or swelling, syncope, jugular venous distention, and finally a pulmonary embolus could be asymptomatic.

We examined the claims data from the December 2015 update of the FY 2015 MedPAR file for ICD–9–CM MS–DRGs 175 and 176 for cases with a principal diagnosis of pulmonary embolism where tPA or other thrombolytic therapy (procedure code 99.10) was administered and cases of a principal diagnosis of pulmonary embolism where no tPA or other thrombolytic therapy was administered. Our findings are shown in the table below.

PRINCIPAL DIAGNOSIS OF PULMONARY EMBOLISM WITH AND WITHOUT tPA OR OTHER THROMBOLYTIC THERAPY ADMINISTERED

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 175—All MCC cases	19,274	5.76	$10,479

PRINCIPAL DIAGNOSIS OF PULMONARY EMBOLISM WITH AND WITHOUT tPA OR OTHER THROMBOLYTIC THERAPY ADMINISTERED—Continued

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 175—MCC cases with principal diagnosis of pulmonary embolism with tPA or other thrombolytic therapy administered	630	6.31	19,419
MS–DRG 175—MCC cases with principal diagnosis of pulmonary embolism without tPA or other thrombolytic therapy administered	18,529	5.74	10,181
MS–DRG 176—All Without MCC cases	33,565	3.81	6,645
MS–DRG 176—Without MCC cases with principal diagnosis of pulmonary embolism with tPA or other thrombolytic therapy administered	544	5.07	16,345
MS–DRG 176—Without MCC cases with principal diagnosis of pulmonary embolism without tPA or other thrombolytic therapy administered	32,789	3.79	6,483

As shown in the table above, for MS–DRG 175, there were a total of 19,274 cases with an average length of stay of 5.76 days and average costs of $10,479. Of the 19,274 cases in MS–DRG 175, there were 630 cases that reported a principal diagnosis of pulmonary embolism where tPA or other thrombolytic therapy was also reported with an average length of stay of 6.31 days and average costs of $19,419. For MS–DRG 176, there were a total of 33,565 cases with an average length of stay of 3.81 days and average costs of $6,645. Of the 33,565 cases reported in MS–DRG 176, there were 544 cases that reported a principal diagnosis of pulmonary embolism where tPA or other thrombolytic therapy also was reported with an average length of stay of 5.07 days and average costs of $16,345.

To address the request we received to create a new MS–DRG, we reviewed the data for the 1,174 total cases (630 and 544, respectively) that reported a principal diagnosis of pulmonary embolism that received tPA or other thrombolytic therapy in MS–DRGs 175 and 176. As shown in the table above, our data analysis demonstrates the average costs for these cases are higher ($19,419 compared to $10,479 for MS–DRG 175, and $16,345 compared to $6,645 for MS–DRG 176) and the length of stay is slightly longer (6.31 days compared to 5.76 days for MS–DRG 175, and 5.07 days compared to 3.81 days for MS–DRG 176) compared to all cases reported in MS–DRGs 175 and 176. Out of a total of 52,492 cases (630 + 18,529 + 544 + 32,789) in MS–DRGs 175 and 176 reporting a principal diagnosis of pulmonary embolism, 1,174 (2.24 percent) of these cases also received tPA or other thrombolytic therapy. While we recognize the differences in average costs and length of stay for these cases, the volume of these cases as well as the potential creation of a new MS–DRG for this subset of patients raised some concerns with our clinical advisors. We present our clinical advisors' concerns following the additional data analysis discussions below.

We then conducted additional data analyses to determine if reassignment of cases with a principal diagnosis of pulmonary embolism where tPA or other thrombolytic therapy was administered to a higher paying MS–DRG was supported. As displayed in the data findings in the tables below, we explored reassigning cases with a principal diagnosis of pulmonary embolism that received tPA or other thrombolytic therapy from MS–DRG 176 to the higher severity level MS–DRG 175. The data do not adequately support this reassignment, as the cases with a principal diagnosis of pulmonary embolism where tPA or other thrombolytic therapy is administered would continue to be underpaid.

As shown in the data findings in the table below, the initial data analysis for MS–DRG 175 found the average costs for cases that reported a principal diagnosis of pulmonary embolism that received tPA or other thrombolytic therapy were $19,419, and for MS–DRG 176, the average costs for these cases were $16,345.

PRINCIPAL DIAGNOSIS OF PULMONARY EMBOLISM WITH tPA OR OTHER THROMBOLYTIC THERAPY ADMINISTERED

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 175—All MCC cases	19,274	5.76	$10,479
MS–DRG 175—MCC cases with principal diagnosis of pulmonary embolism with tPA or other thrombolytic therapy administered	630	6.31	19,419
MS–DRG 176—All without MCC cases	33,565	3.81	6,645
MS–DRG 176—Without MCC cases with principal diagnosis of pulmonary embolism with tPA or other thrombolytic therapy administered	544	5.07	16,345

As displayed in the table below, if we reassigned the 544 cases with a principal diagnosis of pulmonary embolism where tPA or other thrombolytic therapy is administered from the "without MCC" level, MS–DRG 176, to the "with MCC" severity level, MS–DRG 175, the average costs for all cases in MS–DRG 175 would be approximately $10,640. This figure continues to result in a difference of approximately $9,000 for the MCC cases and $6,000 for the without MCC cases when compared to findings for the average costs of these cases from the initial data analysis ($19,419 − $10,640 = $8,779 and $16,345 − $10,640 = $5,705, respectively). In addition, our clinical advisors had concerns about the prospect of moving the subset of 544 patients from the "without MCC" level to the "with MCC" level. We present these concerns following the additional data analysis discussion below.

OPTION OF REASSIGNMENT OF CASES OF PRINCIPAL DIAGNOSIS OF PULMONARY EMBOLISM WITH AND WITHOUT TPA

MS–DRG 175—Cases with pulmonary embolism with MCC or tPA or other thrombolytic therapy	19,818	5.74	$10,640
MS–DRG 176—Cases with pulmonary embolism without MCC	33,021	3.79	6,486

We also reviewed claims data in considering the option of adding another severity level to the current structure of MS–DRGs 175 and 176 and assigning the cases with a principal diagnosis of pulmonary embolism that receive tPA or other thrombolytic therapy to the highest level. This option would involve modifying the current 2-way severity level split of "with MCC" and "without MCC" to a 3-way severity level split of "with MCC or tPA, with CC, and without CC/MCC." Therefore, it would include proposing new MS–DRGs if the data and our clinical advisors supported creation of new MS–DRGs. However, as displayed in the data findings in the table below, the data did not support this option. In addition to similar results from the previous option's discussion regarding continued differences in average costs for these cases, the data failed to meet the criterion that there be at least a $2,000 difference between the "with CC" and "without CC/MCC" subgroups. Our data analysis shows the average costs in the hypothetical "with CC" subgroup of $6,932 and the average costs in the hypothetical "without CC/MCC" subgroup of $5,309. The difference only amounts to $1,623 ($6,932 minus $5,309 = $1,623).

PRINCIPAL DIAGNOSIS OF PULMONARY EMBOLISM WITH AND WITHOUT TPA OR OTHER THROMBOLYTIC THERAPY

Optional new MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG XXX—Pulmonary embolism with MCC or tPA or other thrombolytic therapy	19,819	5.74	$10,641
MS–DRG XXX—Pulmonary embolism with CC	23,929	4.04	6,932
MS–DRG XXX—Pulmonary embolism without CC/MCC	9,091	3.13	5,309

Lastly, we explored reassigning cases with a principal diagnosis of pulmonary embolism that receive tPA or other thrombolytic therapy to other MS–DRGs within MDC 4. However, our review did not support reassignment of these cases to any other medical MS–DRGs as these cases would not be clinically coherent with the cases assigned to those other MS–DRGs.

In addition to the results of the various data analyses we performed for creating a new MS–DRG or for reassignment of cases of pulmonary embolism with tPA or other thrombolytic therapy to another higher paying MS–DRG, our clinical advisors also expressed a number of concerns. They pointed out that all patients with a diagnosis of pulmonary embolism are considered high risk and the small subset of patients receiving thrombolytic therapy does not necessarily warrant a separate MS–DRG or reassignment at this time. Our clinical advisors noted that it is unclear if: (1) The higher costs associated with receiving tPA or other thrombolytic therapy are due to a different subset of patients or complications; (2) if those patients treated with tPA or other thrombolytic therapy for pulmonary embolism are indeed sicker patients; (3) if the cost of tPA or other thrombolytic therapy for patients with pulmonary embolism is the reason for the higher costs seen with these cases; or (4) if the increased average costs for cases of pulmonary embolism with tPA or other thrombolytic therapy is a combination of numbers (1) through (3). They recommended maintaining the current structure of MS–DRGs 175 and 176 at this time.

As a result of the data analysis and the concerns expressed by our clinical advisors, we are not proposing to create a new MS–DRG or to reassign cases with a principal diagnosis of pulmonary embolism with tPA or other thrombolytic therapy for FY 2017. We are inviting public comment on our proposal.

5. MDC 5 (Diseases and Disorders of the Circulatory System)

a. Implant of Loop Recorder

We received a request to examine a potential ICD–9 to ICD–10 replication issue for procedures describing implantation or revision of loop recorder that were reported using ICD–9–CM procedure code 37.79 (Revision or relocation of cardiac device pocket). A loop recorder is also known as an implantable cardiac monitor. It is indicated for patients who experience episodes of unexplained syncope (fainting), heart palpitations, or patients at risk for various types of cardiac arrhythmias, such as atrial fibrillation or ventricular tachyarrhythmia. Loop recorders function by detecting and monitoring potential episodes of these kinds of conditions. The requestor acknowledged that these implantation procedures are frequently performed in the outpatient setting. However, the requestor also noted that the implantation procedures are often performed in the inpatient setting and suggested that they be recognized under the ICD–10 MS–DRGs as they had been under the ICD–9–CM based MS–DRG logic.

The requestor stated that, under the ICD–9–CM based MS–DRGs, procedure code 37.79 was designated as an operating room (O.R.) procedure in the Definitions Manual under Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index and grouped to MS–DRGs 040, 041, and 042 (Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC, with CC or peripheral neurostimulator, and without CC/MCC, respectively); MS–DRGs 260, 261, and 262 (Cardiac Pacemaker Revision Except Device Replacement with MCC, with CC, and without CC/MCC, respectively); MS–DRGs 579, 580, and 581 (Other Skin, Subcutaneous Tissue and Breast Procedures with MCC, with CC and without CC/MCC, respectively); MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively); and MS–DRGs 957, 958, and 959 (Other O.R. Procedures for Multiple Significant Trauma with MCC, with CC, and without CC/MCC, respectively).

Under the current Version 33 ICD–10 MS–DRGs, there are two comparable ICD–10–PCS code translations for ICD–9–CM code 37.79. They are procedure codes 0JWT0PZ (Revision of cardiac rhythm related device in trunk subcutaneous tissue and fascia, open approach) and 0JWT3PZ (Revision of cardiac rhythm related device in trunk subcutaneous tissue and fascia, percutaneous approach), which are designated as O.R. procedures and group to the above listed MS–DRGs.

According to the requestor, the following six ICD–10–PCS procedure codes identify the implantation or revision of a loop recorder and were not replicated appropriately because they are currently designated as nonoperating room (non-O.R.) procedures under the ICD–10 MS–DRGs. The requestor suggested that these codes be designated as O.R. procedures and assigned to the same MS–DRGs as the former ICD–9–CM procedure code 37.79:

ICD–10–PCS procedure code	Description
0JH602Z	Insertion of monitoring device into chest subcutaneous tissue and fascia, open approach.
0JH632Z	Insertion of monitoring device into chest subcutaneous tissue and fascia, percutaneous approach.
0JH802Z	Insertion of monitoring device into abdomen subcutaneous tissue and fascia, open approach.
0JH832Z	Insertion of monitoring device into abdomen subcutaneous tissue and fascia, percutaneous approach.
0JWT02Z	Revision of monitoring device in trunk subcutaneous tissue and fascia, open approach.
0JWT32Z	Revision of monitoring device in trunk subcutaneous tissue and fascia, percutaneous approach.

We examined the six ICD–10–PCS procedure codes that the commenter recommended be designated as O.R. procedures and assigned to the same MS–DRGs as ICD–9–CM procedure code 37.79. As discussed in section II.F.1.b. of the preamble of this proposed rule, in evaluating requested MS–DRG changes, we determined if they could be replicated in the ICD–9–CM MS–DRGs so as not to affect the FY 2017 relative payment weights. If the answer was "no," we examined whether the change in the ICD–10 MS–DRGs was likely to cause a significant number of patient cases to change or "shift" ICD–10 MS–DRGs. If relatively few patient cases would be impacted, we evaluated if it would be feasible to propose the change even though it could not be replicated by the ICD–9 MS–DRGs logic because it would not cause a material payment redistribution.

Under our review, we recognized that the six ICD–10–PCS procedure codes are currently identified as comparable translations of ICD–9–CM procedure code 86.09 (Other incision of skin and subcutaneous tissue), which was designated as a non-O.R. procedure code under the ICD–9–CM based MS–DRGs. Therefore, changing the designation of the six ICD–10–PCS procedure codes from non-O.R. to O.R. for the ICD–10 MS–DRGs cannot be replicated in the ICD–9–CM based MS–DRGs. In other words, we cannot designate ICD–9–CM procedure code 86.09 as an O.R. code. However, we believe that if we limit the change in designation to four of the six identified ICD–10–PCS procedure codes from non-O.R. to O.R., the change would not have any impact. We are not including the two ICD–10–PCS procedure codes that describe the insertion of a monitoring device into the abdomen in our proposal because a loop recorder is not inserted into that location and it would not be clinically appropriate.

Therefore, for FY 2017, we are proposing to designate the following four ICD–10–PCS codes as O.R. procedures within Appendix E of the Version 34 ICD–10 MS–DRG Definitions Manual:

- 0JH602Z (Insertion of monitoring device into chest subcutaneous tissue and fascia, open approach);
- 0JH632Z (Insertion of monitoring device into chest subcutaneous tissue and fascia, percutaneous approach);
- 0JWT02Z (Revision of monitoring device in trunk subcutaneous tissue and fascia, open approach); and
- 0JWT32Z (Revision of monitoring device in trunk subcutaneous tissue and fascia, percutaneous approach).

We also are proposing that the ICD–10 MS–DRG assignment for these four ICD–10–PCS codes replicate the ICD–9–CM based MS–DRG assignment for procedure code 37.79; that is, MS–DRGs 040, 041, 042, 260, 261, 262, 579,580, 581, 907, 908, 909, 957, 958, and 959 as cited earlier in this section.

We are inviting public comments on our proposals.

b. Endovascular Thrombectomy of the Lower Limbs

We received a comment stating that the logic for ICD–10 MS–DRGs Version 33 is not compatible with the ICD–9–CM MS–DRGs Version 32 for the assignment of procedures describing endovascular thrombectomy of the lower limbs. The commenter asked CMS to reconfigure the MS–DRG structure within the ICD–10 MS–DRGs for endovascular thrombectomy of the lower limbs, specifically MS–DRGs 270, 271, and 272 (Endovascular Thrombectomy of the Lower Limbs with MCC, with CC, and without CC/MCC, respectively). The commenter believed that this requested restructuring would be consistent with the MS–DRG assignments for the other procedures describing lower extremity thrombectomy, and would accurately replicate the logic of the ICD–9–CM MS–DRGs Version 32. Under the ICD–9–CM, endovascular thrombectomy of the lower limbs is described by procedure code 39.79 (Other endovascular procedures on other vessels). The commenter stated that, with deep vein thrombosis (DVT) or any other circulatory system disorders as the principal diagnosis, cases involving procedures described by procedure code 39.79 grouped to ICD–9–CM MS–DRGs 237 and 238 (Major Cardiovascular Procedures with and without MCC, respectively). However, the commenter pointed out that, for FY 2016, ICD–9–CM MS–DRGs 237 and 238 were deleted and replaced with ICD–10 Version 33 MS–DRGs 268 and 269 (Aortic and Heart Assist Procedures Except Pulsation Balloon with and without MCC, respectively), for the higher complexity procedures, and MS–DRGs 270, 271, and 272 (Other Major Cardiovascular Procedures with MCC, with CC, and without CC/MCC, respectively), for the lower complexity procedures (80 FR 49389). The commenter stated that ICD–9–CM procedure code 39.79 describes the lower complexity procedures assigned to ICD–10–PCS MS–DRGs 270, 271, and 272. The commenter believed that the comparable ICD–10–PCS procedure codes also should have been assigned to MS–DRGs 270, 271, and 272.

We agree with the requestor that procedures describing endovascular thrombectomy of the lower limbs should be assigned to ICD–10 MS–DRGs 270, 271, and 272. Therefore, for implementation October 1, 2016, we are proposing to restructure the ICD–10–PCS MS–DRG configuration and add the ICD–10–PCS code translations listed in the following chart (which would capture procedures describing endovascular thrombectomy of the lower limbs) to ICD–10–PCS Version 34 MS–DRGs 270, 271, and 272.

ICD–10–PCS ENDOVASCULAR THROMBECTOMY PROCEDURE CODES PROPOSED TO BE ASSIGNED TO MS–DRGS 270, 271, AND 272 FOR FY 2017

03C53ZZ	Extirpation of matter from right axillary artery, percutaneous approach.
03C63ZZ	Extirpation of matter from left axillary artery, percutaneous approach.
03C73ZZ	Extirpation of matter from right brachial artery, percutaneous approach.
03C83ZZ	Extirpation of matter from left brachial artery, percutaneous approach.
03C93ZZ	Extirpation of matter from right ulnar artery, percutaneous approach.
03CA3ZZ	Extirpation of matter from left ulnar artery, percutaneous approach.
03CB3ZZ	Extirpation of matter from right radial artery, percutaneous approach.
03CC3ZZ	Extirpation of matter from left radial artery, percutaneous approach.
03CD3ZZ	Extirpation of matter from right hand artery, percutaneous approach.
03CF3ZZ	Extirpation of matter from left hand artery, percutaneous approach.
03CY3ZZ	Extirpation of matter from upper artery, percutaneous approach.
04CK3ZZ	Extirpation of matter from right femoral artery, percutaneous approach.
04CL3ZZ	Extirpation of matter from left femoral artery, percutaneous approach.
04CM3ZZ	Extirpation of matter from right popliteal artery, percutaneous approach.
04CN3ZZ	Extirpation of matter from left popliteal artery, percutaneous approach.
04CP3ZZ	Extirpation of matter from right anterior tibial artery, percutaneous approach.
04CQ3ZZ	Extirpation of matter from left anterior tibial artery, percutaneous approach.
04CR3ZZ	Extirpation of matter from right posterior tibial artery, percutaneous approach.
04CS3ZZ	Extirpation of matter from left posterior tibial artery, percutaneous approach.
04CT3ZZ	Extirpation of matter from right peroneal artery, percutaneous approach.
04CU3ZZ	Extirpation of matter from left peroneal artery, percutaneous approach.
04CV3ZZ	Extirpation of matter from right foot artery, percutaneous approach.
04CW3ZZ	Extirpation of matter from left foot artery, percutaneous approach.
04CY3ZZ	Extirpation of matter from lower artery, percutaneous approach.
05C73ZZ	Extirpation of matter from right axillary vein, percutaneous approach.
05C83ZZ	Extirpation of matter from left axillary vein, percutaneous approach.
05C93ZZ	Extirpation of matter from right brachial vein, percutaneous approach.
05CA3ZZ	Extirpation of matter from left brachial vein, percutaneous approach.
05CB3ZZ	Extirpation of matter from right basilic vein, percutaneous approach.
05CC3ZZ	Extirpation of matter from left basilic vein, percutaneous approach.
05CD3ZZ	Extirpation of matter from right cephalic vein, percutaneous approach.
05CF3ZZ	Extirpation of matter from left cephalic vein, percutaneous approach.
05CG3ZZ	Extirpation of matter from right hand vein, percutaneous approach.
05CH3ZZ	Extirpation of matter from left hand vein, percutaneous approach.
05CL3ZZ	Extirpation of matter from intracranial vein, percutaneous approach.
05CM3ZZ	Extirpation of matter from right internal jugular vein, percutaneous approach.
05CN3ZZ	Extirpation of matter from left internal jugular vein, percutaneous approach.
05CP3ZZ	Extirpation of matter from right external jugular vein, percutaneous approach.
05CQ3ZZ	Extirpation of matter from left external jugular vein, percutaneous approach.
05CR3ZZ	Extirpation of matter from right vertebral vein, percutaneous approach.
05CS3ZZ	Extirpation of matter from left vertebral vein, percutaneous approach.
05CT3ZZ	Extirpation of matter from right face vein, percutaneous approach.
05CV3ZZ	Extirpation of matter from left face vein, percutaneous approach.
05CY3ZZ	Extirpation of matter from upper vein, percutaneous approach.
06C33ZZ	Extirpation of matter from esophageal vein, percutaneous approach.
06CM3ZZ	Extirpation of matter from right femoral vein, percutaneous approach.
06CN3ZZ	Extirpation of matter from left femoral vein, percutaneous approach.
06CP3ZZ	Extirpation of matter from right greater saphenous vein, percutaneous approach.
06CQ3ZZ	Extirpation of matter from left greater saphenous vein, percutaneous approach.
06CR3ZZ	Extirpation of matter from right lesser saphenous vein, percutaneous approach.
06CS3ZZ	Extirpation of matter from left lesser saphenous vein, percutaneous approach.
06CT3ZZ	Extirpation of matter from right foot vein, percutaneous approach.

We are inviting public comments on our proposal to assign the ICD–10–PCS procedures describing the endovascular thrombectomy of the lower limbs listed in the table above to ICD–10 Version 34 MS–DRGs 270, 271, and 272 for FY 2017.

c. Pacemaker Procedures Code Combinations

We received a request that CMS examine the list of ICD–10–PCS procedure code combinations that describe procedures involving pacemakers to determine if some procedure code combinations were excluded from the ICD–10 MS–DRG assignments for MS–DRGs 242, 243, and 244 (Permanent Cardiac Pacemaker Implant with MCC, with CC, and without CC/MCC). The requestor believed that some ICD–10–PCS procedure code combinations describing procedures involving pacemaker devices and leads are not included in the current list.

We reviewed the list of ICD–10–PCS procedure code combinations describing procedures involving pacemakers assigned to ICD–10 MS–DRGs 242, 243, and 244, and determined that our initial approach of using specified procedure code combinations to identify procedures involving pacemakers and leads was overly complex and may have led to inadvertent omissions of qualifying procedure code combinations. Under our initial approach, we developed a list of possible ICD–10–PCS procedure code combinations that describe procedures involving pacemaker devices and leads as well as ICD–10–PCS procedure code combinations for procedures describing the removal and replacement of pacemaker devices. We now believe that a more appropriate approach would be to compile a list of all procedure codes describing procedures involving pacemaker devices and a list of all procedure codes describing procedures involving pacemaker leads. If a procedure code from the list of procedure codes describing procedures involving pacemaker devices and a procedure code from the list of procedure codes describing procedures involving pacemaker leads are reported in combination with one another, the case would be assigned to ICD–10 MS–DRGs 242, 243, and 244. We believe that this more generic approach would capture a wider range of possible reported procedure codes describing procedures involving pacemaker devices and leads. Therefore, we are proposing to modify the ICD–10 MS–DRG logic so that if one of the ICD–10–PCS procedure codes describing procedures involving pacemaker devices listed in column 1 of the table below is reported in combination with one of the ICD–10–PCS procedure codes describing procedures involving leads listed in column 3 of the table below, the case would be assigned to MS–DRGs 242, 243, and 244. We believe that this proposed simplified approach would capture all possible cases reporting procedure code combinations describing procedures involving pacemaker devices and leads to ensure that these cases would be assigned to MS–DRGs 242, 243, and 244.

ICD–10–PCS Procedure codes describing procedures involving cardiac pacemaker devices (any one code reported from this column list) (1)		In combination with (2)	ICD–10–PCS Procedure codes describing procedures involving cardiac pacemaker leads (any one code reported from this column list) (3)	
Procedure code	Code description		Procedure code	Code description
0JH604Z	Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, open approach.		02H40JZ	Insertion of pacemaker lead into coronary vein, open approach.
0JH605Z	Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, open approach.		02H40MZ	Insertion of cardiac lead into coronary vein, open approach.
0JH606Z	Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, open approach.		02H43JZ	Insertion of pacemaker lead into coronary vein, percutaneous approach.
0JH607Z	Insertion of cardiac resynchronization pacemaker pulse generator into chest subcutaneous tissue and fascia, open approach.		02H43MZ	Insertion of cardiac lead into coronary vein, percutaneous approach.
0JH60PZ	Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, open approach.		02H44JZ	Insertion of pacemaker lead into coronary vein, percutaneous endoscopic approach.
0JH634Z	Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, percutaneous approach.		02H44MZ	Insertion of cardiac lead into coronary vein, percutaneous endoscopic approach.
0JH635Z	Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, percutaneous approach.		02H60JZ	Insertion of pacemaker lead into right atrium, open approach.
0JH636Z	Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, percutaneous approach.		02H60MZ	Insertion of cardiac lead into right atrium, open approach.
0JH637Z	Insertion of cardiac resynchronization pacemaker pulse generator into chest subcutaneous tissue and fascia, percutaneous approach.		02H63JZ	Insertion of pacemaker lead into right atrium, percutaneous approach.
0JH63PZ	Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, percutaneous approach.		02H63MZ	Insertion of cardiac lead into right atrium, percutaneous approach.
0JH804Z	Insertion of pacemaker, single chamber into abdomen subcutaneous tissue and fascia, open approach.		02H64JZ	Insertion of pacemaker lead into right atrium, percutaneous endoscopic approach.
0JH805Z	Insertion of pacemaker, single chamber rate responsive into abdomen subcutaneous tissue and fascia, open approach.		02H64MZ	Insertion of cardiac lead into right atrium, percutaneous endoscopic approach.
0JH806Z	Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, open approach.		02H70JZ	Insertion of pacemaker lead into left atrium, open approach.
0JH807Z	Insertion of cardiac resynchronization pacemaker pulse generator into abdomen subcutaneous tissue and fascia, open approach.		02H70MZ	Insertion of cardiac lead into left atrium, open approach.
0JH80PZ	Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, open approach.		02H73JZ	Insertion of pacemaker lead into left atrium, percutaneous approach.
0JH834Z	Insertion of pacemaker, single chamber into abdomen subcutaneous tissue and fascia, percutaneous approach.		02H73MZ	Insertion of cardiac lead into left atrium, percutaneous approach.

ICD–10–PCS Procedure codes describing procedures involving cardiac pacemaker devices (any one code reported from this column list) (1)		In combination with (2)	ICD–10–PCS Procedure codes describing procedures involving cardiac pacemaker leads (any one code reported from this column list) (3)	
Procedure code	Code description		Procedure code	Code description
0JH835Z	Insertion of pacemaker, single chamber rate responsive into abdomen subcutaneous tissue and fascia, percutaneous approach.	....	02H74JZ	Insertion of pacemaker lead into left atrium, percutaneous endoscopic approach.
0JH836Z	Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, percutaneous approach.	....	02H74MZ	Insertion of cardiac lead into left atrium, percutaneous endoscopic approach.
0JH837Z	Insertion of cardiac resynchronization pacemaker pulse generator into abdomen subcutaneous tissue and fascia, percutaneous approach.	....	02HK0JZ	Insertion of pacemaker lead into right ventricle, open approach.
0JH83PZ	Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, percutaneous approach.	....	02HK0MZ	Insertion of cardiac lead into right ventricle, open approach.
			02HK3JZ	Insertion of pacemaker lead into right ventricle, percutaneous approach.
			02HK3MZ	Insertion of cardiac lead into right ventricle, percutaneous approach.
			02HK4JZ	Insertion of pacemaker lead into right ventricle, percutaneous endoscopic approach.
			02HK4MZ	Insertion of cardiac lead into right ventricle, percutaneous endoscopic approach.
			02HL0JZ	Insertion of pacemaker lead into left ventricle, open approach.
			02HL0MZ	Insertion of cardiac lead into left ventricle, open approach.
			02HL3JZ	Insertion of pacemaker lead into left ventricle, percutaneous approach.
			02HL3MZ	Insertion of cardiac lead into left ventricle, percutaneous approach.
			02HL4JZ	Insertion of pacemaker lead into left ventricle, percutaneous endoscopic approach.
			02HL4MZ	Insertion of cardiac lead into left ventricle, percutaneous endoscopic approach.
			02HN0JZ	Insertion of pacemaker lead into pericardium, open approach.
			02HN0MZ	Insertion of cardiac lead into pericardium, open approach.
			02HN3JZ	Insertion of pacemaker lead into pericardium, percutaneous approach.
			02HN3MZ	Insertion of cardiac lead into pericardium, percutaneous approach.
			02HN4JZ	Insertion of pacemaker lead into pericardium, percutaneous endoscopic approach.
			02HN4MZ	Insertion of cardiac lead into pericardium, percutaneous endoscopic approach.

We are inviting public comments on our proposal to modify the MS–DRG logic for MS–DRGs 242, 243, and 244 to establish that cases reporting one ICD–10–PCS code from the list of procedure codes describing procedures involving pacemaker devices and one ICD–10–PCS code from the list of procedure codes describing procedures involving pacemaker leads in combination with one another would qualify the case for assignment to MS–DRGs 242, 243, and 244.

We also examined our GROUPER logic for MS–DRGs 258 and 259 (Cardiac Pacemaker Device Replacement with and without MCC, respectively). Assignments of cases to these MS–DRGs also include qualifying ICD–10–PCS procedure code combinations describing procedures that involve the removal of pacemaker devices and the insertion of new devices. We believe that this logic may also be overly complex. Moreover, we believe that a more simplified approach would be to compile a list of all ICD–10–PCS procedure codes describing procedures involving cardiac pacemaker device insertions. Therefore, we are proposing this approach for FY 2017. Under the proposed approach, if one of the procedure codes describing procedures involving pacemaker device insertions is reported, and there are no other procedure codes describing procedures involving the insertion of a pacemaker lead reported in combination with one of these procedures, the case would be assigned to MS–DRG 258 and 259. Cases reporting any one of the following ICD–10–PCS procedure codes describing procedures involving pacemaker device insertions would be assigned to MS–DRG 258 and 259.

PROCEDURE CODES DESCRIBING PROCEDURES INVOLVING CARDIAC PACEMAKER DEVICE INSERTIONS REPORTED WITHOUT ANY OTHER PACEMAKER DEVICE PROCEDURE CODE PROPOSED TO BE ASSIGNED TO ICD–10 MS–DRGS 258 AND 259

Procedure code	Description
0JH604Z	Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, open approach.
0JH605Z	Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, open approach.
0JH606Z	Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, open approach.
0JH607Z	Insertion of cardiac resynchronization pacemaker pulse generator into chest subcutaneous tissue and fascia, open approach.
0JH60PZ	Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, open approach.
0JH634Z	Insertion of pacemaker, single chamber into chest subcutaneous tissue and fascia, percutaneous approach.
0JH635Z	Insertion of pacemaker, single chamber rate responsive into chest subcutaneous tissue and fascia, percutaneous approach.
0JH636Z	Insertion of pacemaker, dual chamber into chest subcutaneous tissue and fascia, percutaneous approach.
0JH637Z	Insertion of cardiac resynchronization pacemaker pulse generator into chest subcutaneous tissue and fascia, percutaneous approach.
0JH63PZ	Insertion of cardiac rhythm related device into chest subcutaneous tissue and fascia, percutaneous approach.
0JH804Z	Insertion of pacemaker, single chamber into abdomen subcutaneous tissue and fascia, open approach.
0JH805Z	Insertion of pacemaker, single chamber rate responsive into abdomen subcutaneous tissue and fascia, open approach.
0JH806Z	Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, open approach.
0JH807Z	Insertion of cardiac resynchronization pacemaker pulse generator into abdomen subcutaneous tissue and fascia, open approach.
0JH80PZ	Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, open approach.
0JH834Z	Insertion of pacemaker, single chamber into abdomen subcutaneous tissue and fascia, percutaneous approach.
0JH835Z	Insertion of pacemaker, single chamber rate responsive into abdomen subcutaneous tissue and fascia, percutaneous approach.
0JH836Z	Insertion of pacemaker, dual chamber into abdomen subcutaneous tissue and fascia, percutaneous approach.
0JH837Z	Insertion of cardiac resynchronization pacemaker pulse generator into abdomen subcutaneous tissue and fascia, percutaneous approach.
0JH83PZ	Insertion of cardiac rhythm related device into abdomen subcutaneous tissue and fascia, percutaneous approach.

We are inviting public comments on our proposal to modify the GROUPER logic for MS–DRGs 258 and 259 to establish that a case reporting one procedure code from the above list of ICD–10–PCS procedure codes describing procedures involving pacemaker device insertions without any other procedure codes describing procedures involving pacemaker leads reported would be assigned to MS–DRGs 258 and 259.

We also examined our GROUPER logic for MS–DRGs 260, 261, and 262 (Cardiac Pacemaker Revision Except Device with MCC, with CC, and without CC/MCC, respectively). Cases assigned to MS–DRGs 260, 261, and 262 also include lists of procedure code combinations describing procedures involving the removal of pacemaker leads and the insertion of new leads, in addition to lists of single procedure codes describing procedures involving the insertion of pacemaker leads, removal of devices, and revision of devices. We believe that this logic may also be overly complex. Moreover, we believe that a more simplified approach would be to provide a single list of procedure codes describing procedures involving cardiac pacemaker lead insertions and other related procedures involving device insertions that would be assigned to MS–DRGs 260, 261, and 262. If one of these procedure codes describing procedures involving the insertion of pacemaker leads is reported, and there are no other procedure codes describing procedures involving the insertion of a device reported, the case would be assigned to MS–DRG 260, 261, and 262. We are proposing that the list of ICD–10–PCS procedure codes describing procedures involving pacemaker lead insertion, removal, or revisions and insertion of hemodynamic devices in the following table would be assigned to MS–DRGs 260, 261, and 262. We are simply proposing to use a single list of ICD–10–PCS procedure codes to determine the MS–DRG assignment.

LIST OF PROCEDURE CODES PROPOSED TO BE ASSIGNED TO MS–DRGS 260, 261, AND 262

Procedure code	Description
02H40JZ	Insertion of pacemaker lead into coronary vein, open approach.
02H40MZ	Insertion of cardiac lead into coronary vein, open approach.
02H43JZ	Insertion of pacemaker lead into coronary vein, percutaneous approach.
02H43MZ	Insertion of cardiac lead into coronary vein, percutaneous approach.
02H44JZ	Insertion of pacemaker lead into coronary vein, percutaneous endoscopic approach.
02H44MZ	Insertion of cardiac lead into coronary vein, percutaneous endoscopic approach.
02H60MZ	Insertion of pacemaker lead into right atrium, open approach.
02H63JZ	Insertion of cardiac lead into right atrium, open approach.
02H63MZ	Insertion of pacemaker lead into right atrium, percutaneous approach.
02H64JZ	Insertion of cardiac lead into right atrium, percutaneous approach.
02H64MZ	Insertion of pacemaker lead into right atrium, percutaneous endoscopic approach.
02H70JZ	Insertion of cardiac lead into right atrium, percutaneous endoscopic approach.
02H70MZ	Insertion of pacemaker lead into left atrium, open approach.
02H73JZ	Insertion of cardiac lead into left atrium, open approach.
02H73MZ	Insertion of pacemaker lead into left atrium, percutaneous approach.
02H74JZ	Insertion of cardiac lead into left atrium, percutaneous approach.
02H74MZ	Insertion of pacemaker lead into left atrium, percutaneous endoscopic approach.
02HK00Z	Insertion of cardiac lead into left atrium, percutaneous endoscopic approach.

LIST OF PROCEDURE CODES PROPOSED TO BE ASSIGNED TO MS–DRGS 260, 261, AND 262—Continued

Procedure code	Description
02HK02Z	Insertion of pressure sensor monitoring device into right ventricle, open approach.
02HK0JZ	Insertion of monitoring device into right ventricle, open approach.
02HK0MZ	Insertion of pacemaker lead into right ventricle, open approach.
02HK30Z	Insertion of cardiac lead into right ventricle, open approach.
02HK32Z	Insertion of pressure sensor monitoring device into right ventricle, percutaneous approach.
02HK3JZ	Insertion of monitoring device into right ventricle, percutaneous approach.
02HK3MZ	Insertion of pacemaker lead into right ventricle, percutaneous approach.
02HK40Z	Insertion of cardiac lead into right ventricle, percutaneous approach.
02HK42Z	Insertion of pressure sensor monitoring device into right ventricle, percutaneous endoscopic approach.
02HK4JZ	Insertion of monitoring device into right ventricle, percutaneous endoscopic approach.
02HK4MZ	Insertion of pacemaker lead into right ventricle, percutaneous endoscopic approach.
02HL0JZ	Insertion of cardiac lead into right ventricle, percutaneous endoscopic approach.
02HL0MZ	Insertion of pacemaker lead into left ventricle, open approach.
02HL3JZ	Insertion of cardiac lead into left ventricle, open approach.
02HL3MZ	Insertion of pacemaker lead into left ventricle, percutaneous approach.
02HL4JZ	Insertion of cardiac lead into left ventricle, percutaneous approach.
02HL4MZ	Insertion of pacemaker lead into left ventricle, percutaneous endoscopic approach.
02HN0JZ	Insertion of cardiac lead into left ventricle, percutaneous endoscopic approach.
02HN0MZ	Insertion of pacemaker lead into pericardium, open approach.
02HN3JZ	Insertion of cardiac lead into pericardium, open approach.
02HN3MZ	Insertion of pacemaker lead into pericardium, percutaneous approach.
02HN4JZ	Insertion of cardiac lead into pericardium, percutaneous approach.
02HN4MZ	Insertion of pacemaker lead into pericardium, percutaneous endoscopic approach.
02PA0MZ	Insertion of cardiac lead into pericardium, percutaneous endoscopic approach.
02PA3MZ	Removal of cardiac lead from heart, open approach.
02PA4MZ	Removal of cardiac lead from heart, percutaneous approach.
02PAXMZ	Removal of cardiac lead from heart, percutaneous endoscopic approach.
02WA0MZ	Revision of cardiac lead in heart, open approach.
02WA3MZ	Revision of cardiac lead in heart, percutaneous approach.
02WA4MZ	Revision of cardiac lead in heart, percutaneous endoscopic approach.
0JH600Z	Insertion of hemodynamic monitoring device into chest subcutaneous tissue and fascia, open approach.
0JH630Z	Insertion of hemodynamic monitoring device into chest subcutaneous tissue and fascia, percutaneous approach.
0JH800Z	Insertion of hemodynamic monitoring device into abdomen subcutaneous tissue and fascia, open approach.
0JH830Z	Insertion of hemodynamic monitoring device into abdomen subcutaneous tissue and fascia, percutaneous approach.
0JPT0PZ	Removal of cardiac rhythm related device from trunk subcutaneous tissue and fascia, open approach.
0JPT3PZ	Removal of cardiac rhythm related device from trunk subcutaneous tissue and fascia, percutaneous approach.
0JWT0PZ	Revision of cardiac rhythm related device in trunk subcutaneous tissue and fascia, open approach.
0JWT3PZ	Revision of cardiac rhythm related device in trunk subcutaneous tissue and fascia, percutaneous approach.

We are inviting public comments on our proposal to modify the GROUPER logic for MS–DRGs 260, 261, and 262 so that cases reporting any one of the ICD–10–PCS procedure codes describing procedures involving pacemakers and related procedures and associated devices listed in the table above would be assigned to MS–DRGs 260, 261, and 262.

d. Transcatheter Mitral Valve Repair With Implant

As we did for the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28008 through 28010), for FY 2017, we received a request to modify the MS–DRG assignment for transcatheter mitral valve repair with implant procedures. We refer readers to detailed discussions of the MitraClip® System (hereafter referred to as MitraClip®) for transcatheter mitral valve repair in previous rulemakings, including the FY 2012 IPPS/LTCH PPS proposed rule (76 FR 25822) and final rule (76 FR 51528 through 51529) and the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 27902 through 27903) and final rule (77 FR 53308 through 53310), in response to requests for MS–DRG reclassification, as well as the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27547 through 27552), under the new technology add-on payment policy. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50575), the application for a new technology add-on payment for MitraClip® was unable to be considered further due to lack of FDA approval by the July 1, 2013 deadline.

In the FY 2015 IPPS/LTCH PPS final rule, we finalized our proposal to not create a new MS–DRG or to reassign cases reporting procedures involving the MitraClip® to another MS–DRG (79 FR 49890 through 49892). Under a separate process, the request for a new technology add-on payment for the MitraClip® System was approved (79 FR 49941 through 49946). As discussed in section II.I.4.e. of the preamble of this proposed rule, we are proposing to discontinue the new technology add-on payment for MitraClip® for FY 2017.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49371), we finalized a modification to the MS–DRGs to which the procedure involving the MitraClip® System was assigned. For the ICD–10 based MS–DRGs to fully replicate the ICD–9–CM based MS–DRGs, ICD–10–PCS code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach), which identifies the use of the MitraClip® technology and is the ICD–10–PCS code translation for ICD–9–CM procedure code 35.97 (Percutaneous mitral valve repair with implant), was assigned to new MS–DRGs 273 and 274 (Percutaneous Intracardiac Procedures with and without MCC, respectively) and continued to be assigned to MS–DRGs 231 and 232 (Coronary Bypass with PTCA with MCC and without MCC, respectively). According to the requestor, there are substantial clinical and resource differences between the transcatheter mitral valve repair procedure and other procedures currently grouping to MS–DRGs 273 and 274, which are the focus of the request.

The requestor submitted three options for CMS to consider for FY 2017. The first option was to create a new MS–DRG for endovascular cardiac valve repair with implant; the second option was to reassign cases for the MitraClip® implant from MS–DRGs 273 and 274 to MS–DRGs 266 and 267 (Endovascular Cardiac Valve Replacement with and without MCC, respectively); and the third option was to reassign cases involving the MitraClip® system to another higher paying MS–DRG.

We analyzed claims data from the December 2015 update of the FY 2015 MedPAR file on reported cases of percutaneous mitral valve repair with implant (ICD–9–CM procedure code 35.97) in MS–DRGs 273 and 274. Our findings are shown in the table below.

PERCUTANEOUS MITRAL VALVE REPAIR WITH IMPLANT

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 273—All cases	6,620	8.01	$27,625
MS–DRG 273—Cases with procedure code 35.97	457	7.57	50,560
MS–DRG 274—All cases	14,220	3.46	19,316
MS–DRG 274—Cases with procedure code 35.97	693	2.67	37,686

As shown in the table, the total number of cases reported in MS–DRG 273 was 6,620 and had an average length of stay of 8.01 days and average costs of $27,625. The number of cases reporting the ICD–9–CM procedure code 35.97 in MS–DRG 273 totaled 457 and had an average length of stay of 7.57 days and average costs of $50,560. For MS–DRG 274, there were a total of 14,220 cases with an average length of stay of 3.46 days and average costs of $19,316. There were a total of 693 cases in MS–DRG 274 that reported procedure code 35.97; these cases had an average length of stay of 2.67 days and average costs of $37,686. We recognize that the cases reporting procedure code 35.97 had a shorter length of stay and higher average costs in comparison to all the cases within MS–DRGs 273 and 274.

As stated above, the first option of the requestor was that we create a new MS–DRG for endovascular cardiac valve repair with implant procedures for all cardiac valve repairs. We reviewed the following list of ICD–10–PCS procedure codes that the requestor submitted to comprise this proposed new MS–DRG.

ICD–10–PCS Code	Description
02UF37Z	Supplement aortic valve with autologous tissue substitute, percutaneous approach.
02UF38Z	Supplement aortic valve with zooplastic tissue, percutaneous approach.
02UF3JZ	Supplement aortic valve with synthetic substitute, percutaneous approach.
02UF3KZ	Supplement aortic valve with nonautologous tissue substitute, percutaneous approach.
02UG37Z	Supplement mitral valve with autologous tissue substitute, percutaneous approach.
02UG38Z	Supplement mitral valve with zooplastic tissue, percutaneous approach.
02UG3JZ	Supplement mitral valve with synthetic substitute, percutaneous approach.
02UG3KZ	Supplement mitral valve with nonautologous tissue substitute, percutaneous approach.
02UH37Z	Supplement pulmonary valve with autologous tissue substitute, percutaneous approach.
02UH38Z	Supplement pulmonary valve with zooplastic tissue, percutaneous approach.
02UH3JZ	Supplement pulmonary valve with synthetic substitute, percutaneous approach.
02UH3KZ	Supplement pulmonary valve with nonautologous tissue substitute, percutaneous approach.
02UJ37Z	Supplement tricuspid valve with autologous tissue substitute, percutaneous approach.
02UJ38Z	Supplement tricuspid valve with zooplastic tissue, percutaneous approach.
02UJ3JZ	Supplement tricuspid valve with synthetic substitute, percutaneous approach.
02UJ3KZ	Supplement tricuspid valve with nonautologous tissue substitute, percutaneous approach.

The above list of ICD–10–PCS procedure codes are currently assigned to MS–DRGs 216 through 221 (Cardiac Valve and Other Major Cardiovascular Procedures with and without Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively), with the exception of procedure code 02UG3JZ, which is assigned to MS–DRGs 273 and 274, as noted earlier in this section.

All 16 of the ICD–10–PCS procedure codes submitted by the requester are comparable translations of ICD–9–CM procedure code 35.33 (Annuloplasty), which also grouped to MS–DRGs 216 through 221. However, ICD–10–PCS procedure code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach) is the comparable translation for both ICD–9–CM procedure code 35.33 and ICD–9–CM procedure code 35.97 (Percutaneous mitral valve repair with implant), which grouped to MS–DRGs 273 and 274 as mentioned previously.

Upon review of the 16 ICD–10–PCS procedure codes submitted for consideration by the requestor, we determined that we cannot propose the suggested change because the resulting ICD–10 MS–DRG logic would not be an accurate replication of the ICD–9–CM based MS–DRG logic. Specifically, it is not possible to replicate reassigning the percutaneous annuloplasty codes from ICD–9–CM based MS–DRGs 216 through 221 to a new MS–DRG because we cannot isolate those cases from procedure code 35.33. Under ICD–9–CM, procedure code 35.33 does not differentiate the specific type of approach used to perform the procedure. This is in contrast to the 60 comparable ICD–10 code translations that do differentiate among various approaches (open, percutaneous, and percutaneous endoscopic).

As stated previously, if the ICD–9–CM and ICD–10 versions of the MS–DRGs cease to be replications of each other, the relative payment weights (computed using the ICD–9–CM based MS–DRGs) would be inconsistent with the ICD–10 MS–DRG assignment, which may cause unintended payment redistribution. Therefore, we are not proposing to create a new MS–DRG for transcatheter mitral valve repair with implant procedures for FY 2017.

The second option in the request was to evaluate reassigning cases involving the MitraClip® to MS–DRGs 266 and 267. This option is not supported for the same reasons provided in previous rulemaking regarding differences between valve replacements and valve repairs. Our clinical advisors do not believe that these procedures are clinically coherent or similar in terms of resource consumption because the MitraClip® technology is utilized for a percutaneous mitral valve *repair,* while the other technologies assigned to MS–DRGs 266 and 267 are utilized for transcatheter/endovascular cardiac valve *replacements.* In addition, if cases involving the MitraClip® were reassigned to MS–DRGs 266 and 267, they would be overpaid by approximately $10,000 as shown in the table below. Our clinical advisors agree that we should not propose to reassign endovascular cardiac valve repair procedures to the endovascular cardiac valve replacement MS–DRGs.

ENDOVASCULAR CARDIAC VALVE REPLACEMENT WITH AND WITHOUT MCC

MS–DRG 266—All cases	7,436	8.54	$59,675
MS–DRG 267—All cases	8,480	4.45	47,013

Next, we analyzed claims data from the December 2015 update of the FY 2015 MedPAR file relating to the possible reassignment of cases involving the MitraClip® (identified by ICD–9–CM procedure code 35.97) to MS–DRGs 228, 229, and 230 (Other Cardiothoracic Procedures with MCC, with CC, and without CC/MCC, respectively). However, as shown in the findings in the table below, the claims data did not support this option under the current 3-way severity level split. That is, the data findings based on reassignment of MitraClip® cases (ICD–9–CM procedure code 35.97) to MS–DRGs 228, 229, and 230 did not support the required criterion that there be at least a $2,000 difference between subgroups. A reassignment would not meet the requirement for the "with CC" and "without CC/MCC" subgroups ($34,461 − $33,216 = $1,245).

OTHER CARDIOTHORACIC PROCEDURES (WITH PROCEDURE CODE 35.97)

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 228—with MCC	1,966	11.53	$51,634
MS–DRG 229—with CC	2,318	6.28	34,461
MS–DRG 230—without CC/MCC	709	3.76	33,216

We then performed additional analysis consisting of the base DRG report for MS–DRGs 228, 229 and 230. As shown in the table below, the average costs between the "with CC" and the "without CC/MCC" subgroups no longer meet the criterion that there be at least a 20-percent difference in average costs between subgroups. These data findings support collapsing MS–DRGs 228, 229, and 230 from a 3-way severity level split into a 2-way severity level split (with MCC and without MCC) based on 2 years (FY 2014 and FY 2015) of MedPAR data. This option would involve the deletion of an MS–DRG.

OTHER CARDIOTHORACIC PROCEDURES

MS–DRG	Number of cases FY 2015	Average length of stay FY 2015	Average costs FY 2015	Number of cases FY 2014	Average length of stay FY 2014	Average costs FY 2014
MS–DRG 228—with MCC	1,509	12.73	$51,960	1,486	12.75	$50,688
MS–DRG 229—with CC	1,835	7.16	33,786	1,900	7.46	33,277
MS–DRG 230—without CC/MCC	499	4.52	30,697	443	4.84	31,053

In the additional analysis, we evaluated if reassignment of cases reporting ICD–9–CM procedure code 35.97 to this proposed 2-way severity split was supported. We confirmed that the reassignment of ICD–9–CM procedure code 35.97 could be replicated under the ICD–9 MS–DRGs. We believe that deleting MS–DRG 230, revising MS–DRG 229, and reassigning cases with procedure code 35.97 from MS–DRGs 273 and 274 to this new structure would reflect these procedures more accurately in the ICD–10 MS–DRGs. Our clinical advisors agreed with a proposal to delete MS–DRG 230 and reassign cases involving percutaneous mitral valve repair with implant (MitraClip®) to MS–DRG 228 and revised MS–DRG 229. We believe that this approach would maintain clinical coherence for these MS–DRGs and reflect more appropriate payment for procedures involving percutaneous mitral valve repair. The proposed revisions to the MS–DRGs, which include the MitraClip® cases, are shown in the table below.

OTHER CARDIOTHORACIC PROCEDURES

Proposed revised MS–DRGs	Number of cases	Average length of stay	Average costs
MS–DRG 228—with MCC	1,966	11.53	$51,634
MS–DRG 229—without MCC	3,027	5.69	34,169

For FY 2017, we are proposing to collapse MS–DRGs 228, 229, and 230 from three severity levels to two severity levels by deleting MS–DRG 230 and revising MS–DRG 229. We also are proposing to reassign ICD–9–CM procedure code 35.97 and the cases reporting ICD–10–PCS procedure code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach) from MS–DRGs 273 and 274 to MS–DRG 228 and proposed revised MS–DRG 229. The title of MS–DRG 229 would be modified as follows to reflect the "without MCC" designation. The title of proposed revised MS–DRG 229 would be "Other Cardiothoracic Procedures without MCC". The title for MS–DRG 228 would remain the same: MS–DRG 228 (Other Cardiothoracic Procedures with MCC). We are inviting public comments on our proposals.

We also note that, as discussed earlier in this section, in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49371), ICD–10–PCS code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach) was assigned to MS–DRGs 231 and 232 (Coronary Bypass with PTCA with MCC and without MCC, respectively), in addition to new MS–DRGs 273 and 274, to fully replicate the ICD–9–CM based MS–DRG logic for ICD–9–CM procedure code 35.97. If our proposal in this FY 2017 proposed rule to reassign ICD–10–PCS code 02UG3JZ to MS–DRGs 228 and proposed revised MS–DRG 229 is finalized in the FY 2017 IPPS/LTCH PPS final rule, it will eliminate the need to continue having ICD–10–PCS code 02UG3JZ and ICD–9–CM code 35.97 group to MS–DRGs 231 and 232. This is due to the fact that, currently, MS–DRGs 228, 229, and 230 are listed higher than MS–DRGs 231 through 236 in the surgical hierarchy, as shown in the ICD–9 and ICD–10 MS–DRGs Definitions Manual Files in Appendix D—MS–DRG Surgical Hierarchy by MDC and MS–DRG, which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending.* Therefore, if the proposal is finalized for FY 2017, cases reporting ICD–10–PCS procedure code 02UG3JZ will group to MS–DRGs 228 and revised MS–DRG 229 versus MS–DRGs 231 and 232 because of the surgical hierarchy GROUPER logic.

As a result, we are proposing to remove ICD–10–PCS procedure code 02UG3JZ and ICD–9–CM procedure code 35.97 from the PTCA list in MS–DRGs 231 and 232 (Coronary Bypass with PTCA with MCC and without MCC, respectively) for FY 2017 if the proposal to reassign ICD–9–CM procedure code 35.97 and the cases reporting ICD–10–PCS procedure codes 02UG3JZ from MS–DRGs 273 and 274 to MS–DRGs 228 and proposed revised MS–DRG 229 is finalized. We are inviting public comments on our proposals.

e. MS–DRG 245 (AICD Generator Procedures)

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49369), we stated that we would continue to monitor MS–DRG 245 (AICD Generator Procedures) to determine if the data supported subdividing this base MS–DRG into severity levels. As displayed in the table below, the results of the FY 2015 data analysis showed there were a total of 1,464 cases, with an average length of stay of 5.5 days and average costs of $34,564 for MS–DRG 245.

AICD GENERATOR PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 245	1,464	5.5	$34,564

We applied the five criteria established in the FY 2008 IPPS final rule (72 FR 47169), as described in section II.F.1.b. of the preamble of this proposed rule to determine if it was appropriate to subdivide MS–DRG 245 into severity levels. The table below illustrates our findings.

AICD GENERATOR PROCEDURES

MS–DRG by suggested severity level	Number of cases	Average length of stay	Average costs
MS–DRG 245—with MCC	449	8.37	$40,175
MS–DRG 245—with CC	861	4.59	32,518
MS–DRG 245—without CC/MCC	154	2.86	29,646

Based on our analysis of claims data from the December 2015 update of the FY 2015 MedPAR file, the data findings do not support creating new severity levels. The findings show that the data do not meet the criteria for a 3-way severity level split as the criterion that there be at least a 20-percent difference in average costs between subgroups is not met for the "with CC" and "without CC/MCC" severity levels. We also looked at the prospect of a 2-way severity level split.

AICD GENERATOR PROCEDURES

MS–DRG by suggested severity level	Number of cases	Average length of stay	Average costs
MS–DRG 245—with MCC	449	8.37	$40,175
MS–DRG 245—without MCC	1,015	4.33	32,081

The findings do show that the data are close to meeting the criteria for a 2-way severity level split of "with MCC and without MCC." However, the required criterion that there must be at least 500 cases in the MCC group is not met.

Therefore, for FY 2017, we are not proposing to subdivide MS–DRG 245 into severity levels. We are inviting public comments on our proposal to maintain the current structure for MS–DRG 245.

6. MDC 6 (Diseases and Disorders of the Digestive System): Excision of Ileum

We received a request to analyze an MS–DRG replication issue from the ICD–9–CM based MS–DRGs to the ICD–10 based MS–DRGs for excision procedures performed on the ileum. Under ICD–9–CM, procedure code 45.62 (Other partial resection of small intestine) was assigned to MS–DRGs 329, 330 and 331 (Major Small and Large Bowel Procedures with MCC, with CC, and without CC/MCC, respectively). Under the current ICD–10 MS–DRGs Version 33, ICD–10–PCS procedure code 0DBB0ZZ (Excision of ileum, open approach) is assigned to MS–DRGs 347, 348, and 349 (Anal and Stomal Procedures with MCC, with CC, and without CC/MCC, respectively). The requestor indicated that, despite the variation in terms for "excision" and "resection" between the two code sets, the surgical procedure to remove a portion of the small intestine, whether it is the ileum, duodenum, or jejunum, has not changed and should not result in different MS–DRG assignments when translated from ICD–9–CM to ICD–10.

We agree that this is a replication error. In addition to ICD–10–PCS code 0DBB0ZZ, we also reviewed the MS–DRG assignments for ICD–10–PCS code 0DBA0ZZ (Excision of jejunum, open approach) and determined the MS–DRG assignment for this code resulted in the same replication error. Therefore, we are proposing to reassign ICD–10–PCS codes 0DBB0ZZ and 0DBA0ZZ from MS–DRGs 347, 348, and 349 to MS–DRGs 329, 330, and 331, effective with the ICD–10 MS–DRGs Version 34 on October 1, 2016.

We are inviting public comments on our proposal.

7. MDC 7 (Diseases and Disorders of the Hepatobiliary System and Pancreas): Bypass Procedures of the Veins

We received a request to assign ICD–10–PCS code 06183DY (Bypass portal vein to lower vein with intraluminal device, percutaneous approach) to MDC 7 (Diseases and Disorders of the Hepatobiliary System and Pancreas) under MS–DRGs 405, 406, and 407 (Pancreas Liver and Shunt Procedures with MCC, with CC, and without CC/MCC, respectively). The requestor described this code as capturing a transjugular intrahepatic portosystem shunt procedure. The requestor stated that, under ICD–9–CM, when a procedure for cirrhosis of the liver was performed, the procedure was assigned to ICD–9–CM code 39.1 (Intra-abdominal venous shunt). The requestor noted that when ICD–9–CM procedure code 39.1 is reported with a principal diagnosis of cirrhosis of the liver, the procedure was assigned to MS–DRG 405, 406, or 407 in the ICD–9–CM MS–DRGs.

Currently, ICD–10–PCS procedure code 06183DY is assigned to only MDC 5 (Diseases and Disorders of the Circulatory System) and MS–DRGs 270, 271, and 272 (Other Major Cardiovascular Procedures with MCC, with CC, and without CC/MCC, respectively) under ICD–10 MS–DRGs Version 33. The requestor stated that ICD–10–PCS procedure code 06183DY code should also be assigned to MDC 7 and MS–DRGs 405, 406, and 407 to be consistent with the ICD–9–CM MS–DRGs Version 32.

We analyzed this issue and agree that the ICD–10 MS–DRGs do not fully replicate the ICD–9–CM MS–DRGs. We agree that ICD–10–PCS procedure code 06183DY should be assigned to MDC 7 and MS–DRGs 405, 406, and 407 to replicate the ICD–9–CM MS–DRGs. Our clinical advisors reviewed this issue and also agree that ICD–10–PCS procedure code 06183DY should be assigned to MDC 7 and MS–DRGs 405, 406, and 407. Therefore, we are proposing to assign ICD–10–PCS procedure code 06183DY to MDC 7 and MS–DRGs 405, 406, and 407 for FY 2017.

We are inviting public comments on our proposal.

8. MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)

a. Proposed Updates to MS–DRGs 469 and 470 (Major Joint Replacement or Reattachment of Lower Extremity With and Without MCC, respectively)

(1) Total Ankle Replacement (TAR) Procedures

We received a request to create a new MS–DRG for total ankle replacement (TAR) procedures, which are currently assigned to MS–DRGs 469 and 470 (Major Joint Replacement or Reattachment of Lower Extremity with and without MCC, respectively). We previously discussed requested changes to the MS–DRG assignment for TAR procedures in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28013 through 28015) and in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49896 through 49899). For FY 2015, we did not change the MS–DRG assignment for total ankle replacements. The requestor stated that reassigning total ankle replacement procedures from MS–DRGs 469 and 470 to a new MS–DRG would have an important benefit for the new Medicare Comprehensive Care for Joint Replacement (CJR) model. The commenter noted that because total ankle replacement cases currently are assigned to MS–DRGs 469 and 470, they are included in the model.

Ankle replacement procedures were captured by ICD–9–CM code 81.56 (Total ankle replacement). We examined claims data for total ankle procedures using the December 2015 update of the FY 2015 MedPAR file. Our findings are displayed in the table below.

Total Ankle Replacement Cases Reported in MS–DRGs 469 and 470

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 469—All cases	25,729	6.92	$22,358
MS–DRG 469—Total ankle replacement cases	30	5.40	34,889
MS–DRG 470—All cases	421,149	2.92	14,834
MS–DRG 470—Total ankle replacement cases	1,626	1.94	20,019

As the total ankle replacement claims data analysis showed, these procedures represent a small fraction of the total number of cases reported in MS–DRGs 469 and 470. There were 30 total ankle replacement cases reported in MS–DRG 469 and 1,626 total ankle replacement cases in MS–DRG 470, compared to 25,729 total cases reported in MS–DRG 469 and 421,149 total cases reported in MS–DRG 470. The average length of stay for total ankle replacement cases was 5.40 days and average costs for total ankle replacement cases were $34,889 reported in MS–DRG 469, compared to average length of stay of 6.92 days and average costs of $22,358 for all cases reported in MS–DRG 469. The average length of stay for total ankle replacement cases was 1.94 days and average costs of total ankle replacement cases were $20,019 reported in MS–DRG 470, compared to an average length of stay of 2.92 days and average costs of $14,834 for all cases reported in MS–DRG 470.

Given the low volume of cases, we believe that these cost data may not be a complete measure of actual differences in inpatient resource utilization for beneficiaries receiving total ankle replacements. In addition, these total ankle replacement cases may have been impacted by other factors such as complication or comorbidities. Several expensive cases could impact the average costs for a very small number of patients. The average cost of total ankle replacement cases reported in MS–DRG 469 was $12,531 higher than all cases reported in MS–DRG 469 ($34,889 compared to $22,358 for all reported cases), but there were only 30 cases compared to a total of 25,729 cases reported in MS–DRG 469. The average cost of total ankle replacement cases reported in MS–DRG 470 was $5,185 higher than all cases reported in MS–DRG 470. There were 1,626 total ankle replacement cases out of a total of 421,149 cases reported in MS–DRG 470. The average costs of the total ankle replacement cases were higher than those for all cases reported in MS–DRG 469 and 470. However, some cases have higher and some cases have lower average costs within any MS–DRG. MS–DRGs are groups of clinically similar cases that have similar overall costs. Within a group of cases, one would expect that some cases have costs that are higher than the overall average and some cases have costs that are lower than the overall average.

The data do not support creating a new total ankle replacement MS–DRG for this small number of cases. Also, our clinical advisors pointed out that creating a new MS–DRG for total ankle replacements would result in combining cases reporting an MCC with an average length of stay of 5.40 days and cases not reporting an MCC with an average length of stay of 1.94 days. Our clinical advisors did not recommend the creation of a new MS–DRG for this single procedure with such a small number of cases. They also stated that patients undergoing total ankle replacement have similar clinical features compared to other patients undergoing procedures included in MS–DRGs 469 and 470. Furthermore, we believe that the volume of total ankle replacement procedures performed relative to hip and knee replacement procedures minimizes the benefit that a new MS–DRG would have on the Medicare CJR model. Our clinical advisors determined that the cases involving total ankle replacements are more appropriately assigned to MS–DRGs 469 and 470 with the two severity levels.

Based on the findings from our data analysis and the recommendations from our clinical advisors, we are not proposing to create a new MS–DRG for total ankle replacement procedures. We are proposing to maintain the current MS–DRG structure for MS–DRGs 469 and 470.

We are inviting public comments on this proposal.

(2) Hip Replacement Procedures With Principal Diagnosis of Hip Fracture

We received several requests to remove hip replacement procedures with a principal diagnosis of hip fracture from MS–DRGs 469 and 470 (Major Joint Replacement or Reattachment of Lower Extremity with and without MCC, respectively) and to create a new MS–DRG for assignment of these hip replacement procedures. One requestor suggested that if such a new MS–DRG could not be created, CMS consider reassigning all hip replacement procedures with a principal diagnosis of hip fracture only to MS–DRG 469, even if there were no reported MCC.

The requestors stated that hip replacement procedures performed on patients with hip fractures involve a more fragile population of patients than the typical patient population who undergo elective hip or knee replacement and that these more fragile patient cases also are assigned to MS–DRGs 469 and 470. The requestors stated that cases of patients who have hip replacements with hip fractures may have significant comorbidities not present in patients who undergo elective hip replacements. One requestor stated that the absolute number of hospitalizations for hip fractures in the United States is currently more than 350,000 and the number is rising. The requestor stated that 90 percent of hip fractures result from a simple fall, and that hip fracture rates increase with age. According to the requestor, the 1-year mortality rate for patients who undergo hip replacement procedures after a hip fracture was approximately 20 percent, and the 3-year mortality rate was up to 50 percent. The requestor also stated that one out of three adults who lived independently before their hip fracture remains in a nursing home for at least a year after the hip fracture. In contrast, the requestor noted that patients under elective hip replacement procedures for arthritis have fewer comorbidities, improved health after the procedure, low rates of readmission, and less postacute needs. The requestor believed that there are many factors that impact the outcome of hip replacements for hip fractures, including patient factors, fracture type, surgeon and hospital factors, treatment decisions, complication rates, and rehabilitation factors/access. The requestor added that, despite the commitment to standardization, the use of protocol-driven care, early surgery (<24 hours) after surgical optimization, prevention of recurrent fractures, and comanagement with medical/surgical teams, many patients who undergo hip replacement procedures for hip fractures have serious renal, cardiovascular, and liver disease, as well as multiple medical comorbidities. The rates of postoperative infections, readmissions, and postacute care for the patients who undergo hip replacements for hip fractures are higher than for patients who undergo elective hip replacement. Some requestors referenced the Bundled Payments for Care Improvement Initiative (BPCI) and believed that their requested changes to MS–DRGs 469 and 470 would support this effort. The requestors stated that the MS–DRG assignment for the hip replacement procedures with hip fractures has tremendous implications for successful participation in the BPCI because the BPCI's clinical episodes track to MS–DRG assignment, and the Major Joint Replacement of the Lower Extremity Clinical Episode encompasses procedures assigned to MS–DRGs 469 and 470. Alternatively, the requestors suggested that CMS reassign all cases of hip replacement procedures with a principal diagnosis of hip fracture to MS–DRG 469 to recognize the more significant adverse health profile of these types of cases.

We examined claims data for cases reporting hip replacement procedures for patients admitted with hip fractures under MS–DRGs 469 and 470 in the December 2015 update of the FY 2015 MedPAR file. We used the following list of ICD–9–CM diagnosis codes to identify cases representing hip replacements for hip fractures:

ICD–9–CM DIAGNOSIS CODES REVIEWED FOR CASES REPRESENTING HIP REPLACEMENT FOR HIP FRACTURES

ICD–9–CM diagnosis code	Descriptions
733.14	Pathological fracture of neck of femur.
733.15	Pathological fracture of other specified part of femur.
733.81	Malunion of fracture.
733.82	Nonunion of fracture.
733.96	Stress fracture of femoral neck.
808.0	Closed fracture of acetabulum.
808.1	Open fracture of acetabulum.
820.8	Fracture of unspecified part of neck of femur closed.
820.9	Fracture of unspecified part of neck of femur open.
820.00	Fracture of unspecified intracapsular section of neck of femur closed.
820.01	Fracture of epiphysis (separation) (upper) of neck of femur closed.
820.02	Fracture of midcervical section of femur closed.
820.03	Fracture of base of neck of femur closed.
820.09	Other transcervical fracture of femur closed.
820.10	Fracture of unspecified intracapsular section of neck of femur open.
820.11	Fracture of epiphysis (separation) (upper) of neck of femur open.
820.12	Fracture of midcervical section of femur open.
820.13	Fracture of base of neck of femur open.
820.19	Other transcervical fracture of femur open.
820.20	Fracture of unspecified trochanteric section of femur closed.
820.21	Fracture of intertrochanteric section of femur closed.
820.22	Fracture of subtrochanteric section of femur closed.
820.30	Fracture of unspecified trochanteric section of femur open.
820.31	Fracture of intertrochanteric section of femur open.
820.32	Fracture of subtrochanteric section of femur open.

Our findings from our examination of the data are shown in the table below.

CASES OF HIP REPLACEMENTS WITH AND WITHOUT PRINCIPAL DIAGNOSIS OF HIP FRACTURE

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 469—All cases	25,729	6.9	$22,358
MS–DRG 469—Hip replacement cases with hip fractures	14,459	7.9	22,852
MS–DRG 469—Hip replacement cases without hip fractures	4,714	5.7	22,430
MS–DRG 470—All cases	421,149	2.9	14,834
MS–DRG 470—Hip replacement cases with hip fractures	49,703	4.7	15,795
MS–DRG 470—Hip replacement cases without hip fractures	125,607	2.6	14,870

For MS–DRG 469, the average costs of all 25,729 reported cases were $22,358 and the average length of stay was 6.9 days. Within MS–DRG 469, there were 14,459 cases of hip replacements with hip fractures reported, with average costs of $22,852 and an average length of stay of 7.9 days. Within MS–DRG 469, there were 4,714 cases of hip replacements without hip fractures reported, with average costs of $22,430 and an average length of stay of 5.7 days. The average costs of reported cases of hip replacements with hip fractures are similar to the average costs of all cases reported within MS–DRG 469 ($22,852 compared to $22,358), and to the average costs of reported cases of hip replacements without hip fractures ($22,852 compared to $22,430). However, the average length of stay for cases of hip replacements with hip fractures reported in MS–DRG 469 is higher than the average length of stay for all cases reported in MS–DRG 469 and for cases of hip replacements without hip fractures reported in MS–

DRG 469 (7.9 days compared to 6.9 days and 5.7 days, respectively.)

For MS–DRG 470, the average costs of all 421,149 cases reported were $14,834 and the average length of stay was 2.9 days. Within MS–DRG 470, there were 49,703 reported cases of hip replacements with hip fractures, with average costs $15,795 and an average length of stay of 4.7 days. Within MS–DRG 470, there were 125,607 cases of hip replacements without hip fractures reported, with average costs of $14,870 and an average length of stay of 2.6 days. However, the average length of stay for cases of hip replacements with hip fractures reported in MS–DRG 470 was higher than the average length of stay for all cases and for cases of hip replacements without hip fractures reported in MS–DRG 470 (4.7 days compared to 2.9 days and 2.6 days, respectively). Therefore, the average costs of cases of hip replacements with hip fractures were similar for both MS–DRG 469 and MS–DRG 470 ($22,852 compared to $22,358 and $15,795 compared to $14,834, respectively). However, the average lengths of stay are longer for cases of hip replacements with hip fractures compared to all cases reported in both MS–DRGs 469 and 470 (7.9 days compared to 6.9 days and 4.7 days compared to 2.9 days, respectively).

The claims data do not support creating a new MS–DRG for the assignment of cases of hip replacements with hip fractures. As discussed earlier, the average costs for cases of hip replacements with hip fractures reported in MS–DRG 469 and MS–DRG 470 are similar to the average costs for all cases reported in MS–DRG 469 and MS–DRG 470. While the average length of stay is longer for cases of hip replacements with hip fractures than for cases of hip replacements without hip fractures reported within MS–DRGs 469 and 470, the increased length of stay did not impact the average costs of reported cases in either MS–DRG 469 or 470. The data showed that cases of hip replacement procedures are clearly influenced by the presence of an MCC. The average costs of all cases reported in MS–DRG 469, which identifies an MCC, were $22,358, compared to average costs of $14,834 for all cases reported in MS–DRG 470, which did not identify an MCC. The data showed that the presence of a principal diagnosis of a hip fracture did not impact the average costs of cases reported in either MS–DRG 469 or MS–DRG 470.

We also examined the data in relation to the request to reassign all procedures of hip replacement with hip fractures from MS–DRG 470 to MS–DRG 469, even if there is no MCC present. The data showed that the 49,703 cases of hip replacements with hip fractures reported in MS–DRG 470 have average costs of $15,795 and an average length of stay of 4.7 days. The 25,729 total cases of hip replacements reported in MS–DRG 469 have average costs of $22,358 and an average length of stays of 6.9 days. Therefore, the data for average costs and average length of stay for all cases involving hip replacement procedures with hip fractures reported in MS–DRG 470 do not support reassigning all cases of hip replacement procedures with hip fractures to MS–DRG 469, even if there is no MCC present.

Our clinical advisors reviewed this issue and agree that the hip replacement procedures performed for patients with hip fractures are appropriately assigned to MS–DRGs 469 and 470. They did not support reassigning these procedures from MS–DRGs 469 and 470 to a new MS–DRG or reassigning all cases of hip replacement procedures with hip fractures to MS–DRG 469, even if the case does not have an MCC. Our clinical advisors stated that the surgical techniques used for hip replacements are similar for all patients. They advised that the fact that some patients also had a hip fracture would not justify creating a new MS–DRG or reassigning all cases of hip replacement procedures with hip fractures to MS–DRG 469. Our clinical advisors noted that the costs of cases of hip replacements are more directly impacted by the presence or absence of an MCC than the presence or absence of a hip fracture.

Based on the findings from our data analyses and the recommendations from our clinical advisors, we are not proposing to create a new MS–DRG for the assignment of procedures involving hip replacement in patients who have hip fractures or to reassign all procedures involving hip replacements with hip fractures to MS–DRG 469 even if there is no MCC present. We are proposing to maintain the current MS–DRG structure for MS–DRGs 469 and 470.

We are inviting public comments on our proposals.

b. Revision of Total Ankle Replacement Procedures

(1) Revision of Total Ankle Replacement Procedures

We received a request to modify the MS–DRG assignment for revision of total ankle replacement procedures. Currently, these procedures are assigned to MS–DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC and without CC/MCC, respectively). This topic was discussed in the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28013 through 28015) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 49896 through 49899). However, at that time, we did not change the MS–DRG assignment for revisions of total ankle replacement procedures.

The requestor presented two options for consideration for modifying the MS–DRG assignment for the revisions of total ankle replacement procedures. The requestor's first option was to create a new MS–DRG for the assignment of revision of total ankle replacement procedures. The requestor believed that a new MS–DRG would be justified based on the distinct costs, resources, and utilization associated with ankle joint revision cases. The requestor's second option was to reassign revision of total ankle replacement procedures to MS–DRGs 466, 467, and 468 (Revision of Hip or Knee Replacement with MCC, with CC, and without CC/MCC, respectively) and rename MS–DRGs 466, 467, and 468 as "Revision of Hip, Knee, or Ankle with MCC, with CC, and without CC/MCC", respectively. The requestor believed that this second option would be justified because it is a reasonable, temporary approach until CMS has sufficient utilization and cost data for revision of total ankle replacement procedures based on the reporting of the new and more specific ICD–10–PCS procedure codes. The requestor pointed out that the following more specific ICD–10–PCS procedure codes were implemented effective October 1, 2015, with the implementation of ICD–10. The requestor stated that these new codes will provide improved data on these procedures that can be analyzed for future MS–DRG updates.

ICD–10–PCS procedure code	Description
0SWF0JZ	Revision of synthetic substitute in right ankle joint, open approach.
0SWF3JZ	Revision of synthetic substitute in right ankle joint, percutaneous approach.
0SWF4JZ	Revision of synthetic substitute in right ankle joint, percutaneous endoscopic approach.

ICD–10–PCS procedure code	Description
0SWFXJZ	Revision of synthetic substitute in right ankle joint, external approach.
0SWG0JZ	Revision of synthetic substitute in left ankle joint, open approach.
0SWG3JZ	Revision of synthetic substitute in left ankle joint, percutaneous approach.
0SWG4JZ	Revision of synthetic substitute in left ankle joint, percutaneous endoscopic approach.
0SWGXJZ	Revision of synthetic substitute in left ankle joint, external approach.

We agree with the requestor that the previous code used to identify revisions of total ankle replacement procedures, ICD–9–CM procedure code 81.59 (Revision of joint replacement of lower extremity, not elsewhere classified), is not as precise as the new ICD–10–PCS procedure codes that were implemented on October 1, 2015. As discussed in the FY 2015 IPPS/LTCH PPS proposed rule and final rule, ICD–9–CM procedure code 81.59 included procedures involving revisions of joint replacements of a variety of lower extremity joints, including the ankle, foot, and toe. Therefore, the ICD–9–CM procedure code does not provide precise information on the number of revisions of total ankle replacement procedures as do the ICD–10–PCS procedure codes listed above. We also agree that the ICD–10–PCS procedure codes will provide more precise data on revisions of ankle replacements.

We examined claims data from the December 2015 update of the FY 2015 MedPAR file on cases reporting procedure code 81.59 in MS–DRGs 515, 516, and 517. The table below shows our findings.

REVISIONS OF JOINT REPLACEMENTS PROCEDURES

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 515—All cases	3,852	8.54	$21,900
MS–DRG 515—Cases reporting procedure code 81.59	2	7.00	36,983
MS–DRG 516—All cases	8,567	5.24	14,839
MS–DRG 516—Cases reporting procedure code 81.59	19	3.74	14,957
MS–DRG 517—All cases	5,664	3.20	12,979
MS–DRG 517—Cases reporting procedure code 81.59	47	1.89	16,524

As can be seen from the data in the above table, there were only 68 total cases reported with procedure code 81.59 among MS–DRGs 515, 516, and 517: 2 Cases in MS–DRG 515; 19 cases in MS–DRG 516; and 47 in MS–DRG 517. We point out that while there were 68 total cases reported with procedure code 81.59 in MS–DRGs 515, 516, and 517, we are unable to determine how many of these cases were actually revisions of ankle replacements versus other revisions of joint replacement of lower extremities such as those of the foot or toe. This small number of cases does not justify creating a new MS–DRG as suggested by the requestor in its first option.

While the average costs of cases reporting procedure code 81.59 in MS–DRG 515 were $36,983, compared to $21,900 for all cases reported in MS–DRG 515, there were only 2 cases reporting procedure code 81.59 in MS–DRG 515, of the 3,852 total cases reported in MS–DRG 515. In MS–DRG 516, the average costs of the 19 cases reporting procedure code 81.59 cases were $14,957, which is very close to the average costs of $14,839 for all 8,567 cases reported in MS–DRG 516. The average costs for cases reporting procedure code 81.59 in MS–DRG 517 were higher than the average costs for all cases reported in MS–DRG 517 ($16,524 for cases reporting procedure code 81.59 cases compared to $12,979 for all cases reported in MS–DRG 517). While the average costs for cases reporting procedure code 81.59 were $3,545 higher than all cases reported in MS–DRG 517, we point out that there were only 47 cases that reported procedure code 81.59 out of the 5,664 total cases reported in MS–DRG 517. The relatively small number of cases may have been impacted by other factors. Several expensive cases could impact the average costs for a very small number of patients.

As stated by the requestor, we do not yet have data using the more precise ICD–10–PCS revisions of total ankle replacement procedure codes that were implemented on October 1, 2015. These new codes will more precisely identify the number of patients who had a revision of total ankle replacement procedure and the number of patients who had revisions of other lower joint replacement procedures such as the foot or toe. The available clinical data from the December 2015 update of the FY 2015 MedPAR file do not support the creation of a new MS–DRG for the assignment of revisions of total ankle replacement procedures or the reassignment of these cases to other MS–DRGs, such as MS–DRGs 466, 467, and 468, because there were so few cases and because we could not determine how many of these cases were revisions of ankle replacements. Claims data on the ICD–10–PCS codes will not be available until 2 years after the implementation of the codes, which was October 1, 2015.

Our clinical advisors reviewed this issue and determined that the revision of total ankle replacement procedures are appropriately classified within MS–DRGs 515, 516, and 517 along with other orthopedic procedures captured by nonspecific codes. They do not support reassignment of the procedures to MS–DRGs 466, 467, and 468 until such time as detailed data for ICD–10–PCS claims are available to evaluate revision of total ankle replacement procedures. Therefore, based on the findings of our analysis of claims data and the advice of our clinical advisors, we are proposing to maintain the current MS–DRG assignment for revision of total ankle replacement procedures for FY 2017.

We are inviting public comments on our proposal.

(2) Combination Codes for Removal and Replacement of Knee Joints

We received several requests asking CMS to examine whether additional combinations of procedure codes for the removal and replacements of knee joints should be added to MS–DRGs 466, 467, and 468 (Revision of Hip or Knee Replacement with MCC, with CC, and without CC/MCC, respectively). This topic was discussed in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24379 through 24395) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49390 through 49406). One requestor stated that the procedure codes in the following table were not included in the code pairs that group to MS–DRGs 466, 467, and 468 in the ICD–10 MS–DRGs Version 33.

ICD–10–PCS procedure code	Description
0SPD08Z	Removal of spacer from left knee joint, open approach.
0SPD38Z	Removal of spacer from left knee joint, percutaneous approach.
0SPD48Z	Removal of spacer from left knee joint, percutaneous endoscopic approach.
0SPC08Z	Removal of spacer from right knee joint, open approach.
0SPC38Z	Removal of spacer from right knee joint, percutaneous approach.
0SPC48Z	Removal of spacer from right knee joint, percutaneous approach.

Other requestors stated that the procedure codes in the following table are not included in the list of combinations that group to MS–DRGs 466, 467, and 468 when reported in conjunction with an ICD–10–PCS code for the removal of synthetic substitute from the joint in the ICD–10 MS–DRGs Version 33.

ICD–10–PCS procedure code	Description
0SRC0J9	Replacement of right knee joint with synthetic substitute, cemented, open approach.
0SRC0JA	Replacement of right knee joint with synthetic substitute, uncemented, open approach.
0SRC0JZ	Replacement of right knee joint with synthetic substitute, open approach.
0SRC07Z	Replacement of right knee joint with autologous tissue substitute, open approach.
0SRC0KZ	Replacement of right knee joint with nonautologous tissue substitute, open approach.

We agree that the joint revision cases involving the removal of a spacer and subsequent insertion of a new knee joint prosthesis should be assigned to MS–DRGs 466, 467, and 468. We examined knee joint revision combination codes that are not currently assigned to MS–DRGs 466, 467, and 468 in ICD–10 MS–DRGs Version 33 and identified 58 additional combinations that also should be included so that the same logic is used in the ICD–10 version of the MS–DRGs as is used in the ICD–9–CM version. We are proposing to add the following 58 new code combinations that capture the joint revisions to the Version 34 MS DRG structure for MS–DRGs 466, 467, and 468, effective October 1, 2016.

ICD–10–PCS Code Pairs Proposed To Be Added to Version 34 ICD–10 MS–DRGs 466, 467, and 468: Proposed New Knee Revision ICD–10–PCS Combinations

Code	Code description		Code	Code description
0SPC08Z	Removal of Spacer from Right Knee Joint, Open Approach.	and	0SRC0J9	Replacement of Right Knee Joint with Synthetic Substitute, Cemented, Open Approach.
0SPC08Z	Removal of Spacer from Right Knee Joint, Open Approach.	and	0SRC0JA	Replacement of Right Knee Joint with Synthetic Substitute, Uncemented, Open Approach.
0SPC08Z	Removal of Spacer from Right Knee Joint, Open Approach.	and	0SRC0JZ	Replacement of Right Knee Joint with Synthetic Substitute, Open Approach.
0SPC08Z	Removal of Spacer from Right Knee Joint, Open Approach.	and	0SRT0J9	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Cemented, Open Approach.
0SPC08Z	Removal of Spacer from Right Knee Joint, Open Approach.	and	0SRT0JA	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPC08Z	Removal of Spacer from Right Knee Joint, Open Approach.	and	0SRT0JZ	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Open Approach.
0SPC08Z	Removal of Spacer from Right Knee Joint, Open Approach.	and	0SRV0J9	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Cemented, Open Approach.
0SPC08Z	Removal of Spacer from Right Knee Joint, Open Approach.	and	0SRV0JA	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPC08Z	Removal of Spacer from Right Knee Joint, Open Approach.	and	0SRV0JZ	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Open Approach.
0SPC38Z	Removal of Spacer from Right Knee Joint, Percutaneous Approach.	and	0SRC0J9	Replacement of Right Knee Joint with Synthetic Substitute, Cemented, Open Approach.
0SPC38Z	Removal of Spacer from Right Knee Joint, Percutaneous Approach.	and	0SRC0JA	Replacement of Right Knee Joint with Synthetic Substitute, Uncemented, Open Approach.
0SPC38Z	Removal of Spacer from Right Knee Joint, Percutaneous Approach.	and	0SRC0JZ	Replacement of Right Knee Joint with Synthetic Substitute, Open Approach.

ICD–10–PCS CODE PAIRS PROPOSED TO BE ADDED TO VERSION 34 ICD–10 MS–DRGS 466, 467, AND 468: PROPOSED NEW KNEE REVISION ICD–10–PCS COMBINATIONS—Continued

Code	Code description		Code	Code description
0SPC38Z	Removal of Spacer from Right Knee Joint, Percutaneous Approach.	and	0SRT0J9	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Cemented, Open Approach.
0SPC38Z	Removal of Spacer from Right Knee Joint, Percutaneous Approach.	and	0SRT0JA	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPC38Z	Removal of Spacer from Right Knee Joint, Percutaneous Approach.	and	0SRT0JZ	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Open Approach.
0SPC38Z	Removal of Spacer from Right Knee Joint, Percutaneous Approach.	and	0SRV0J9	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Cemented, Open Approach.
0SPC38Z	Removal of Spacer from Right Knee Joint, Percutaneous Approach.	and	0SRV0JA	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPC38Z	Removal of Spacer from Right Knee Joint, Percutaneous Approach.	and	0SRV0JZ	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Open Approach.
0SPC48Z	Removal of Spacer from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRC0J9	Replacement of Right Knee Joint with Synthetic Substitute, Cemented, Open Approach.
0SPC48Z	Removal of Spacer from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRC0JA	Replacement of Right Knee Joint with Synthetic Substitute, Uncemented, Open Approach.
0SPC48Z	Removal of Spacer from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRC0JZ	Replacement of Right Knee Joint with Synthetic Substitute, Open Approach.
0SPC48Z	Removal of Spacer from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRT0J9	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Cemented, Open Approach.
0SPC48Z	Removal of Spacer from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRT0JA	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPC48Z	Removal of Spacer from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRT0JZ	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Open Approach.
0SPC48Z	Removal of Spacer from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRV0J9	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Cemented, Open Approach.
0SPC48Z	Removal of Spacer from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRV0JA	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPC48Z	Removal of Spacer from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRV0JZ	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Open Approach.
0SPC4JZ	Removal of Synthetic Substitute from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRT0JZ	Replacement of Right Knee Joint, Femoral Surface with Synthetic Substitute, Open Approach.
0SPC4JZ	Removal of Synthetic Substitute from Right Knee Joint, Percutaneous Endoscopic Approach.	and	0SRV0JZ	Replacement of Right Knee Joint, Tibial Surface with Synthetic Substitute, Open Approach.
0SPD08Z	Removal of Spacer from Left Knee Joint, Open Approach.	and	0SRD0J9	Replacement of Left Knee Joint with Synthetic Substitute, Cemented, Open Approach.
0SPD08Z	Removal of Spacer from Left Knee Joint, Open Approach.	and	0SRD0JA	Replacement of Left Knee Joint with Synthetic Substitute, Uncemented, Open Approach.
0SPD08Z	Removal of Spacer from Left Knee Joint, Open Approach.	and	0SRD0JZ	Replacement of Left Knee Joint with Synthetic Substitute, Open Approach.
0SPD08Z	Removal of Spacer from Left Knee Joint, Open Approach.	and	0SRU0JA	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Cemented, Open Approach.
0SPD08Z	Removal of Spacer from Left Knee Joint, Open Approach.	and	0SRU0JA	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPD08Z	Removal of Spacer from Left Knee Joint, Open Approach.	and	0SRU0JZ	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Open Approach.
0SPD08Z	Removal of Spacer from Left Knee Joint, Open Approach.	and	0SRW0J9	Replacement of Left Knee Joint, Tibial Surface with Synthetic Substitute, Cemented, Open Approach.
0SPD08Z	Removal of Spacer from Left Knee Joint, Open Approach.	and	0SRW0JA	Replacement of Left Knee Joint, Tibial Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPD08Z	Removal of Spacer from Left Knee Joint, Open Approach.	and	0SRW0JZ	Replacement of Left Knee Joint, Tibial Surface with Synthetic Substitute, Open Approach.
0SPD38Z	Removal of Spacer from Left Knee Joint, Percutaneous Approach.	and	0SRD0J9	Replacement of Left Knee Joint with Synthetic Substitute, Cemented, Open Approach.
0SPD38Z	Removal of Spacer from Left Knee Joint, Percutaneous Approach.	and	0SRD0JA	Replacement of Left Knee Joint with Synthetic Substitute, Uncemented, Open Approach.
0SPD38Z	Removal of Spacer from Left Knee Joint, Percutaneous Approach.	and	0SRD0JZ	Replacement of Left Knee Joint with Synthetic Substitute, Open Approach.

ICD–10–PCS CODE PAIRS PROPOSED TO BE ADDED TO VERSION 34 ICD–10 MS–DRGS 466, 467, AND 468: PROPOSED NEW KNEE REVISION ICD–10–PCS COMBINATIONS—Continued

Code	Code description		Code	Code description
0SPD38Z	Removal of Spacer from Left Knee Joint, Percutaneous Approach.	and	0SRU0JA	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Cemented, Open Approach.
0SPD38Z	Removal of Spacer from Left Knee Joint, Percutaneous Approach.	and	0SRU0JA	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPD38Z	Removal of Spacer from Left Knee Joint, Percutaneous Approach.	and	0SRU0JZ	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Open Approach.
0SPD38Z	Removal of Spacer from Left Knee Joint, Percutaneous Approach.	and	0SRW0J9	Replacement of Left Knee Joint, Tibial Surface with Synthetic Substitute, Cemented, Open Approach.
0SPD38Z	Removal of Spacer from Left Knee Joint, Percutaneous Approach.	and	0SRW0JA	Replacement of Left Knee Joint, Tibial Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPD38Z	Removal of Spacer from Left Knee Joint, Percutaneous Approach.	and	0SRW0JZ	Replacement of Left Knee Joint, Tibial Surface with Synthetic Substitute, Open Approach.
0SPD48Z	Removal of Spacer from Left Knee Joint, Percutaneous Endoscopic Approach.	and	0SRD0J9	Replacement of Left Knee Joint with Synthetic Substitute, Cemented, Open Approach.
0SPD48Z	Removal of Spacer from Left Knee Joint, Percutaneous Endoscopic Approach.	and	0SRD0JA	Replacement of Left Knee Joint with Synthetic Substitute, Uncemented, Open Approach.
0SPD48Z	Removal of Spacer from Left Knee Joint, Percutaneous Endoscopic Approach.	and	0SRD0JZ	Replacement of Left Knee Joint with Synthetic Substitute, Open Approach.
0SPD48Z	Removal of Spacer from Left Knee Joint, Percutaneous Endoscopic Approach.	and	0SRU0JA	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Cemented, Open Approach.
0SPD48Z	Removal of Spacer from Left Knee Joint, Percutaneous Endoscopic Approach.	and	0SRU0JA	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPD48Z	Removal of Spacer from Left Knee Joint, Percutaneous Endoscopic Approach.	and	0SRU0JZ	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Open Approach.
0SPD48Z	Removal of Spacer from Left Knee Joint, Percutaneous Endoscopic Approach.	and	0SRW0J9	Replacement of Left Knee Joint, Tibial Surface with Synthetic Substitute, Cemented, Open Approach.
0SPD48Z	Removal of Spacer from Left Knee Joint, Percutaneous Endoscopic Approach.	and	0SRW0JA	Replacement of Left Knee Joint, Tibial Surface with Synthetic Substitute, Uncemented, Open Approach.
0SPD48Z	Removal of Spacer from Left Knee Joint, Percutaneous Endoscopic Approach.	and	0SRW0JZ	Replacement of Left Knee Joint, Tibial Surface with Synthetic Substitute, Open Approach.
0SPD4JZ	Removal of Synthetic Substitute from Left Knee Joint, Percutaneous Endoscopic Approach.	and	0SRU0JZ	Replacement of Left Knee Joint, Femoral Surface with Synthetic Substitute, Open Approach.

We are inviting public comments on our proposal to add the joint revision code combinations listed above to the ICD–10 Version 34 MS–DRGs 466, 467, and 468.

c. Decompression Laminectomy

Currently, under ICD–10–PCS, the procedure describing a decompression laminectomy is coded for the "release" of a specified area of the spinal cord. These decompression codes are assigned to MS–DRGs 028, 029, and 030 (Spinal Procedures with MCC, with CC or Spinal Neurostimulators, or without CC/MCC, respectively) and to MS–DRGs 518, 519, and 520 (Back and Neck Procedures Except Spinal Fusion with MCC or Disc Device or Neurostimulator, with CC, or without CC/MCC, respectively) in the ICD–10 MS–DRGs Version 33. A commenter brought to our attention that codes describing release of specific peripheral nerve are assigned to MS–DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC, and without CC/MCC, respectively). The commenter suggested that a subset of these codes also be assigned to MS–DRGs 028 through 030 and MS–DRGs 518 through 520 for clinical coherence purposes. The commenter stated, for example, that ICD–10–PCS procedure code 00NY0ZZ (Release lumbar spinal cord, open approach) is assigned to MS–DRGs 028 through 030 and MS–DRGs 518 through 520. However, ICD–10–PCS procedure code 01NB0ZZ (Release lumbar nerve, open approach) is assigned to MS–DRGs 515 through 517.

We agree with the commenter's suggestion. Therefore, for FY 2017, we are proposing to reassign the ICD–10–PCS procedure codes listed in the following table from MS–DRGs 515 through 517 to MS–DRGs 028 through 030 and MS–DRGs 518 through 520 under the ICD–10 MS–DRGs Version 34.

ICD–10–PCS procedure code	Description
01N00ZZ	Release cervical plexus, open approach.
01N03ZZ	Release cervical plexus, percutaneous approach.
01N04ZZ	Release cervical plexus, percutaneous endoscopic approach.
01N10ZZ	Release cervical nerve, open approach.
01N13ZZ	Release cervical nerve, percutaneous approach.

ICD–10–PCS procedure code	Description
01N14ZZ	Release cervical nerve, percutaneous endoscopic approach.
01N80ZZ	Release thoracic nerve, open approach.
01N83ZZ	Release thoracic nerve, percutaneous approach.
01N84ZZ	Release thoracic nerve, percutaneous endoscopic approach.
01N90ZZ	Release lumbar plexus, open approach.
01N93ZZ	Release lumbar plexus, percutaneous approach.
01N94ZZ	Release lumbar plexus, percutaneous endoscopic approach.
01NA0ZZ	Release lumbosacral plexus, open approach.
01NA3ZZ	Release lumbosacral plexus, percutaneous approach.
01NA4ZZ	Release lumbosacral plexus, percutaneous approach.
01NB0ZZ	Release lumbar nerve, open approach.
01NB3ZZ	Release lumbar nerve, percutaneous approach.
01NB4ZZ	Release lumbar nerve, percutaneous endoscopic approach.

We are inviting public comments on our proposal.

d. Lordosis

An ICD–10 replication issue involving four diagnosis codes related to lordosis (excessive curvature of the lower spine) was discovered in MS–DRGs 456, 457, and 458 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions with MCC, with CC, and without CC/MCC). These MS–DRGs contain specific logic that requires a principal diagnosis describing a spinal curvature, a malignancy, or infection or a secondary diagnosis that describes a spinal curvature disorder related to another condition.

Under the ICD–10 MS–DRGs Version 33, the following diagnosis codes were listed on the principal diagnosis list and the secondary diagnosis list for MS–DRGs 456, 457, and 458:

- M40.50 (Lordosis, unspecified, site unspecified);
- M40.55 (Lordosis, unspecified, thoracolumbar region);
- M40.56 (Lordosis, unspecified, lumbar region); and
- M40.57 (Lordosis, unspecified, lumbosacral region).

We are proposing to remove the above four diagnosis codes from the secondary diagnosis list. We also are proposing to maintain these same four codes in the logic for the principal diagnosis list. This proposed change for MS–DRGs 456, 457, and 458 would be effective October 1, 2016, in the ICD–10 MS–DRGs Version 34.

We are inviting public comments on our proposals.

9. MDC 13 (Diseases and Disorders of the Female Reproductive System): Pelvic Evisceration

In the ICD–10 MS–DRG Definitions Manual Version 33, the GROUPER logic for ICD–10 MS–DRGs 332, 333, and 334 (Rectal Resection with MCC, with CC and without CC/MCC, respectively) under MDC 6 (Diseases and Disorders of the Digestive System) and the GROUPER logic for MS–DRGs 734 and 735 (Pelvic Evisceration, Radical Hysterectomy and Radical Vulvectomy with CC/MCC and without CC/MCC, respectively) under MDC 13 (Diseases and Disorders of the Female Reproductive System) include a "cluster" of ICD–10–PCS procedure codes that describe pelvic evisceration. A "cluster" is the term used to describe a circumstance when a combination of ICD–10–PCS procedure codes is needed to fully satisfy the equivalent meaning of an ICD–9–CM procedure code for it to be considered a plausible code translation. The code cluster in MS–DRGs 332, 333, and 334 and MS–DRGs 734 and 735 is shown in the table below.

ICD–10–PCS procedure code in cluster	Description
0TTB0ZZ	Resection of bladder, open approach.
0TTD0ZZ	Resection of urethra, open approach.
0UT20ZZ	Resection of bilateral ovaries, open approach.
0UT70ZZ	Resection of bilateral fallopian tubes, open approach.
0UT90ZZ	Resection of uterus, open approach.
0UTC0ZZ	Resection of cervix, open approach.
0UTG0ZZ	Resection of vagina, open approach.

Pelvic evisceration (or exenteration) is a procedure performed to treat gynecologic cancers (cervical, uterine, vulvar, and vaginal, among others) and involves resection of pelvic structures such as the procedures described by the cluster of procedure codes listed above.

Under the ICD–9–CM MS–DRGs Version 32, procedure code 68.8 (Pelvic evisceration) was used to report pelvic evisceration. ICD–9–CM procedure code 68.8 also was assigned to ICD–9–CM MS–DRGs 332, 333, and 334 and MS–DRGs 734 and 735 in MDCs 6 and 13, respectively. The inclusion term in the ICD–9–CM Tabular List of Diseases for pelvic evisceration (procedure code 68.8) was "Removal of ovaries, tubes, uterus, vagina, bladder, and urethra (with removal of sigmoid colon and rectum)." In the ICD–9–CM Tabular List, the terms shown in parentheses are called a "non-essential modifier". A "non-essential modifier" is used in the classification to identify a supplementary word that may, or may not, be present in the statement of a disease or procedure. In other words, the terms in parentheses do not have to be documented to report the code.

Because the removal of sigmoid colon and the removal of rectum were classified as non-essential modifiers under ICD–9–CM, documentation that identified that removal of those body sites occurred was not required to report the procedure code describing pelvic evisceration (procedure code 68.8). In other words, when a pelvic evisceration procedure was performed and included removal of other body sites (ovaries and tubes, among others) listed in the inclusion term, *absent* the terms in parentheses, procedure code 68.8 could be reported and grouped appropriately to MDC 13 under MS–DRGs 734 and 735. When a pelvic evisceration procedure was performed and removal of the body sites listed in the inclusion term occurred, *including* the terms in parentheses, procedure code 68.8 could be reported and grouped appropriately to MDC 6 under MS–DRGs 332 through 334.

Under ICD–10–PCS, users are instructed to code separately the organs or structures that are actually removed and for which there is a distinctly defined body part. Therefore, the case of a patient who undergoes a pelvic evisceration (exenteration) that involves the removal of the sigmoid colon and rectum would have each of those procedure sites (sigmoid colon and rectum) coded and reported separately (in addition to the procedure codes displayed in the cluster). In this scenario, if the principal diagnosis is a condition from the MDC 6 diagnosis list, the case would group to MS–DRGs 332, 333, and 334, regardless of the code cluster. In other words, it would not be necessary to retain the code cluster describing procedures performed on female pelvic organs in MDC 6.

Therefore, for FY 2017, we are proposing to remove the procedure code cluster for pelvic evisceration procedures from MDC 6 under the ICD–10 MS–DRGs Version 34. The cluster would remain in ICD–10 MDC 13 under MS–DRGs 734 and 735 only. We are inviting public comments on our proposal.

10. MDC 19 (Mental Diseases and Disorders): Proposed Modification of Title of MS–DRG 884 (Organic Disturbances and Mental Retardation)

We received a request to change the title of MS–DRG 884 (Organic Disturbances and Mental Retardation) under MDC 19 (Mental Diseases and Disorders) to "MS–DRG 884 (Organic Disturbances and Intellectual Disability)" to reflect more recent terminology used to appropriately describe the latter medical condition in the MDC.

We agree with the requestor that the reference to the phrase "Mental Retardation" should be changed to "Intellectual Disability", to reflect the current terminology used to describe the condition. Therefore, we are proposing to change the title of MS–DRG 884 as requested by the requestor.

We are inviting public comments on our proposal to change the title of MS–DRG 884 from "Organic Disturbances and Mental Retardation" to "Organic Disturbances and Intellectual Disability", effective October 1, 2016, in the ICD–10 MS–DRGs Version 34.

11. MDC 23 (Factors Influencing Health Status and Other Contacts With Health Services): Logic of MS–DRGs 945 and 946 (Rehabilitation With and Without CC/MCC, Respectively)

We received several requests to examine the MS–DRG logic for MS–DRGs 945 and 946 (Rehabilitation with CC/MCC and without CC/MCC, respectively). The requestors were concerned that ICD–9–CM codes that clearly identified an encounter for rehabilitation services such as procedure codes V57.89 (Care involving other specified rehabilitation procedure) and V57.9 (Care involving unspecified rehabilitation procedure) were not included in ICD–10–CM Version 33. In addition, the requestors pointed out that ICD–10–CM has significantly changed the guidelines for coding of admissions/encounters for rehabilitation. The requestors pointed out that under ICD–9–CM, Section I.B.15. of the Official Guidelines for Coding and Reporting indicates that "when the purpose for the admission/encounter is rehabilitation, sequence the appropriate V code from category V57, Care involving use of rehabilitation procedures, as the principal/first listed diagnosis." The requestors stated that the concept of the ICD–9–CM category V57 codes is no longer valid in ICD–10–CM and the guidelines have been revised to provide greater specificity. Instead, the requestors added, the ICD–10–CM guidelines state in Section II.K., "When the purpose for the admission/encounter is rehabilitation, sequence first the code for the condition for which the service is being performed. For example, for an admission/encounter for rehabilitation for right-sided dominant hemiplegia following a cerebrovascular infarction, report code I69.351, Hemiplegia and hemiparesis following cerebral infarction affecting right dominant side, as the first-listed or principal diagnosis."

Given this lack of ICD–10–CM codes to indicate that the reason for the encounter was for rehabilitation, some requesters asked that CMS review ICD–10–CM codes for conditions requiring rehabilitation (such as codes from category I69) and add them to MS–DRGs 945 and 946 when rehabilitation services are provided in order to replicate the logic found in the ICD–9–CM MS-DRG GROUPER. The requestors did not suggest any specific ICD–10–CM codes to add to MS–DRGs 945 and 946.

One requestor made a specific recommendation for updating MS–DRGs 945 and 946. The requestor previously recommended that CMS review diagnosis codes in ICD–10–CM category I69 for possible addition to MS–DRGs 945 and 946. The requestor stated that, upon further review, they believe that a great number of diagnosis codes beyond sequelae of stroke (ICD–10–CM category I69) would need to be added in order to replicate the logic of the ICD–9–CM MS–DRGs. Therefore, they modified their recommendation as follows:

- Designate MS–DRGs 945 and 946 as pre-major diagnostic categories (Pre-MDC) MS–DRGs so that cases are grouped to these MS–DRGs on the basis of the procedure code rather than the principal diagnosis. The requestor stated that the ICD–10–PCS rehabilitation codes (Section F, Physical Rehabilitation and Diagnostic Audiology, Body system 0, Rehabilitation) should be used to group cases to MS–DRGs 945 and 946 similar to how the MS–DRG GROUPER logic currently treats lung transplants and tracheostomies. This would ensure that the rehabilitation procedure codes drive the MS–DRG assignment.
- Revise ICD–10–PCS Official Guidelines for Coding and Reporting and designate that the ICD–10–PCS rehabilitation codes be used only for admissions for rehabilitation therapy.

We acknowledge that ICD–10–CM does not have clear diagnosis codes that indicate the reason for the encounter was for rehabilitation services. For that reason, CMS had to modify the MS–DRG logic using ICD–10–PCS procedure codes to assign these cases to MS–DRGs 945 and 946. The logic used in MS–DRGs 945 and 946 is shown in the Definitions Manual Version 33, which is posted on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending*. We also posted a Frequently Asked Question section to explain how inpatient admissions are assigned to MS–DRGs 945 and 946, which is posted on the CMS Web site at: *https://questions.cms.gov/faq.php?id=5005&faqId=12548*. As indicated in the Frequently Asked Question section, the ICD–10–CM codes required a different approach to make sure the same cases captured with ICD–9–CM codes would be captured with ICD–10–CM codes. As stated earlier, ICD–10–CM does not contain specific codes for encounters for rehabilitation such as ICD–9–CM procedure codes V57.89 and V57.9. In order to replicate the ICD–9–CM MS–DRG logic using ICD–10–CM and ICD–

10–PCS codes, CMS developed the new logic included in the MS–DRG Version 33 Definitions Manual.

The Frequently Asked Question section explains that, in order to be assigned to ICD–10 MS–DRG 945 or 946, a case must first have a principal diagnosis from MDC 23 (Factors Influencing Health Status and Other Contacts with Health Services), where MS–DRGs 945 and 946 are assigned. This is currently the logic with the ICD–9–CM MS–DRGs Version 33 where one would first have to have a MDC 23 principal diagnosis. A complete list of ICD–10–CM principal diagnoses for MDC 23 can be found in the ICD–10 MS–DRGs Version 33 Definitions Manual which is posted on the FY 2016 IPPS Final Rule Home Page under the link for the FY 2016 Final Rule Data Files at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Final-Rule-Data-Files.html.* Look under the Related Links section and select the ICD–10–CM/PCS MS–DRG v33 Definitions Manual Table of Contents Full Titles HTML Version file. Open this file and the Table of Contents page will appear. Click on the link for MDC 23 (Factors Influencing Health Status and Other Contacts with Health Services). On the next page that opens (MDC 23), click on the link titled "MDC 23 Assignment of Diagnosis Codes" on the upper left side of the screen. By using the navigation arrows at the top right hand side of the page, users can review the 24 pages listing all of the principal diagnosis codes assigned to MDC 23, including many injury codes for subsequent encounters.

Under the GROUPER Logic, cases are assigned to MS–DRGs 945 and 946 in one of two ways as described in the Definitions Manual as follows:

- The encounter has a principal diagnosis code Z44.8 (Encounter for fitting and adjustment of other external prosthetic devices) or Z44.9 (Encounter for fitting and adjustment of unspecified external prosthetic device). Both of these codes are included in the list of principal diagnosis codes assigned to MDC 23.
- The encounter has an MDC 23 principal diagnosis code and one of the rehabilitation procedure codes listed under MS–DRGs 945 and 946.

If the case does not have a principal diagnosis code from the MDC 23 list, but does have a procedure code from the list included under the Rehabilitation Procedures for MS–DRGs 945 and 946, the case will not be assigned to MS–DRGs 945 or 946. The case will instead be assigned to a MS–DRG within the MDC where the principal diagnosis code is found.

Example: The encounter has a principal diagnosis code of S02119D (Unspecified fracture of occiput, subsequent encounter for fracture with routine healing). This code is included in MDC 8. Therefore, diagnosis code S02119D and a procedure code from the MS–DRG 945 and 946 Rehabilitation Procedure list, such as procedure code F0706GZ (Therapeutic Exercise Treatment of Neurological System—Head and Neck using Aerobic Endurance and Conditioning Equipment) would not lead to assignment of the case to MS–DRGs 945 and 946 because the principal diagnosis code is not included in MDC 23.

Diagnosis code S02119D is included in MDC 8 as was the ICD–9–CM predecessor code, V54.19 (Aftercare for healing traumatic fracture of other bone). Therefore, these cases would be assigned to MS–DRGs 559, 560, and 561 (Aftercare, Musculoskeletal System and Connective Tissue with MCC, with CC, and without MCC/CC, respectively) within MDC 8.

At this time, we do not have any claims data that indicate how well this MS–DRG logic is working. We are hesitant to simply add more codes from category I69 without evaluating the impact of doing so using claims data. We also do not have claims data to indicate whether or not there have been changes in the types or numbers of cases assigned to MS–DRGs 945 and 946. We welcome specific suggestions of codes to be added to MS–DRGs 945 and 946 based on hospitals' experience in coding these cases. We would evaluate these suggestions once we have claims data to study the impact.

We have major concerns about the recommendation to revise the ICD–10–PCS Official Guidelines for Coding and Reporting and designate that the ICD–10–PCS rehabilitation codes be assigned and reported only for admissions for rehabilitation therapy. This would be a major new precedent for developing coding and reporting guidelines based on one specific payer's payment polices, in this case Medicare inpatient acute care prospective payment system policies. Hospitals would need to know who the payer was prior to knowing whether or not they could assign a code for a rehabilitation service that they provided. If those payment policies change, the hospital coder would need to be aware of those changes in order to determine whether or not they could submit a code that captures the fact that a rehabilitation service was provided. CMS has worked with the Centers for Disease Control and Prevention (CDC), the American Hospital Association (AHA), and the American Health Information Management Association (AHIMA) to make ICD–10–PCS guidelines generic and applicable to all types of inpatient facilities and for all payer types. The current ICD–10–PCS Guidelines for Coding and Reporting do not support this recommendation that rehabilitation services could only be coded and reported if the admission was specifically for rehabilitation therapy. The ICD–10–PCS codes were created to accurately capture services provided.

We also have concerns about designating MS–DRGs 945 and 946 as pre-MDCs so that cases are grouped to these MS–DRGs on the basis of a rehabilitation procedure code rather than a principal diagnosis. Pre-MDCs were an addition to Version 8 of the Diagnosis Related Groups. This was the first departure from the use of principal diagnosis as the initial variable in DRG and subsequently MS–DRG assignment. For Pre-MDC DRGs, the initial step in DRG assignment was not the principal diagnosis, but was instead certain surgical procedures with extremely high costs such as heart transplant, liver transplant, bone marrow transplant, and tracheostomies performed on patients on long-term ventilation. These types of services were viewed as being very resource intensive. Recognizing these resource intensive services and assigning them to one of the high-cost MS–DRGs assures appropriate payment even if the patient is admitted for a variety of principal diagnoses. We believe it is inappropriate to consider rehabilitation services in the same group as high-cost procedures such as heart transplants. There is the significant potential of patients being classified out of higher paying surgical MS–DRGs in other MDCs and into the lower paying MS–DRGs 945 and 946 based on the reporting of a rehabilitation procedure code if these MS–DRGs are moved to the Pre-MDCs. We examined claims data for cases reporting a rehabilitation therapy code and found cases assigned to a wide variety of both medical and surgical MS–DRGs. The current coding and reporting of rehabilitation procedure codes for services provided suggest the potential of significant payment problems if MS–DRGs 945 and 946 were assigned to the Pre-MDC section and the reporting of cases with a rehabilitation code led to an inappropriate reassignment to the lower paying medical MS–DRGs 945 and 946.

The following are only a few examples of current claims data that showed the hospital reported a rehabilitation therapy procedure code for services provided which did not impact the MS–DRG assignment. Under the suggested approach of making MS–

DRGs 945 and 946 a Pre-MDC, these cases would move from the appropriately assigned MS–DRGs which may have significantly higher average costs, to MS–DRGs 945 and 946, which have much lower average costs. Based on claims data from the December 2015 update of the FY 2015 MedPAR file, the average costs for cases reported in MS–DRGs 945 and 946 were $8,531 and $8,411, respectively.

Examples of cases reporting a rehabilitation therapy code that would move to MS–DRGs 945 and 946 based on the suggested logic change are as follows:

- An MS–DRG 460 (Spinal Fusion Except Cervical with MCC) case with average costs of $42,390;
- An MS–DRG 464 (Wound Debridement and Skin Graft Excluding Hand, for Musculoskeletal Tissue Disease with CC) case with average costs of $55,633;
- An MS–DRG 579 (Other Skin, Subcutaneous Tissue and Breast Procedure with MCC) case with average costs of $63,834;
- An MS–DRG 854 (Infectious and Parasitic Diseases with O.R. procedure with MCC) case with average costs of $62,455; and
- An MS–DRG 021 (Intracranial Vascular Procedures with Principal Diagnosis of Hemorrhage with CC) case with average costs of $90,522.

Our clinical advisors reviewed this issue and agreed that we should wait for ICD–10 claims data to become available prior to proposing updates to MS–DRGs 945 and 946. They did not support adding MS–DRGs 945 and 946 to the Pre-MDCs because the rehabilitation services are not as resource intensive as are the other MS–DRGs in the Pre-MDC section.

Considering these ICD–10–PCS guideline concerns, the structure of the pre-MDC section, and the lack of any ICD–10 claims data for MS–DRGs 945 and 946, we are proposing to maintain the current structure of MS–DRGs 945 and 946 and reconsider the issue when ICD–10 claims data become available and prior to proposing any updates.

We are inviting public comments on our proposal to maintain the current structure of MS–DRGs 945 and 946.

12. Proposed Medicare Code Editor (MCE) Changes

The Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare claims data. Patient diagnoses, procedure(s), and demographic information are entered into the Medicare claims processing systems and are subjected to a series of automated screens. The MCE screens are designed to identify cases that require further review before classification into an MS–DRG.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49409 through 49412), we finalized the ICD–10 Definitions of Medicare Code Edits (ICD–10 MCE) Version 33. ICD–10 MCE Version 33 was based on the FY 2015 ICD–9–CM MCE Version 32 and the draft ICD–10 MCE Version 32 that had been made publicly available for comments in November 2014 on the ICD–10 MS–DRG Conversion Project Web site at: *https://www.cms.gov/Medicare/Coding/ICD10/ICD-10-MS-DRG-Conversion-Project.html.* In August 2015, we posted the finalized FY 2016 ICD–10 MCE Version 33 manual file and an ICD–9–CM MCE Version 33.0A manual file (for analysis purposes only). The links to these MCE manual files, along with the links to purchase the mainframe and computer software for the MCE Version 33 (and ICD–10 MS–DRGs) were posted on the CMS Web site through the FY 2016 IPPS Final Rule Home Page at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page.html?DLSort=0&DLEntries=10&DLPage=1&DLSortDir=ascending.*

After implementation of the ICD–10 MCE Version 33, we received several requests to examine specific code edit lists that the requestors believed were incorrect and that affected claims processing functions. We received requests to review the MCE relating specifically to the Age conflict edit, the Sex conflict edit, the Non-covered procedure edit, and the Unacceptable principal diagnosis code edit. We discuss these code edit issues below.

a. Age Conflict Edit

In the MCE, the Age conflict edit exists to detect inconsistencies between a patient's age and any diagnosis on the patient's record; for example, a 5-year-old patient with benign prostatic hypertrophy or a 78-year-old patient coded with a delivery. In these cases, the diagnosis is clinically and virtually impossible for a patient of the stated age. Therefore, either the diagnosis or the age is presumed to be incorrect. Currently, in the MCE, the following four age diagnosis categories appear under the Age conflict edit and are listed in the manual and written in the software program:

- Newborn—Age of 0 years; a subset of diagnoses intended only for newborns and neonates (*e.g.,* fetal distress, perinatal jaundice).
- Pediatric—Age is 0–17 years inclusive (*e.g.,* Reye's syndrome, routine child health exam).
- Maternity—Age range is 12–55 years inclusive (*e.g.,* diabetes in pregnancy, antepartum pulmonary complication).
- Adult—Age range is 15–124 years inclusive (*e.g.,* senile delirium, mature cataract).

(1) Newborn Diagnosis Category

Under the ICD–10–CM Official Guidelines for Coding and Reporting (available on the Web site at: *https://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-CM-and-GEMs.html*), there are general guidelines and chapter-specific coding guidelines. The chapter-specific guidelines state that diagnosis codes from Chapter 16 (Certain Conditions Originating in the Perinatal Period) may be reported throughout the life of the patient if the condition is still present. The requestors noted that several codes from this Chapter 16 appear on the ICD–10 MCE Version 33 Age conflict edit for the newborn diagnosis category. Codes from this chapter are included in the P00 through P96 code range. Therefore, the requestors believed that because the chapter-specific guidelines state that codes within this chapter may be reported throughout the life of a patient, all codes within this range (P00 through P96) should be removed from the newborn diagnosis category on the Age conflict edit code list.

We examined the newborn diagnosis category on the age conflict edit list in the ICD–9–CM MCE Version 32 in comparison to the ICD–9–CM chapter-specific guidelines. Under ICD–9–CM, Chapter 15 (Certain Conditions Originating in the Perinatal Period) includes codes within the 760 through 779 range. We found that the same chapter-specific guideline under ICD–10 exists under ICD–9–CM: Diagnosis codes from Chapter 15 may be reported throughout the life of the patient if the condition is still present. Similar to the ICD–10 MCE Version 33 newborn diagnosis category in the Age conflict edit code list, we noted that several codes from this Chapter 15 appear on the ICD–9–CM MCE Version 32 Age conflict edit for the newborn diagnosis category.

Because the full definition of the chapter-specific guideline for "Certain Conditions Originating in the Perinatal Period" clearly states the codes within the chapter may be reported throughout the life of the patient *if the condition is still present,* we believe that, historically, under ICD–9–CM, this was the rationale for inclusion of the diagnosis codes that were finalized for the newborn diagnosis category under the Age conflict edit (in code range 760 through 779). For example, under ICD–9–CM, there are four diagnosis codes in the 760.6x series that specifically include the term "newborn" in the title. These diagnosis codes are:

- 760.61 (Newborn affected by amniocentesis);
- 760.62 (Newborn affected by other in utero procedure);
- 760.63 (Newborn affected by other surgical operations on mother during pregnancy); and
- 760.64 (Newborn affected by previous surgical procedure on mother not associated with pregnancy).

Under the ICD–9–CM classification, the chapter-specific guidelines in Chapter 15 (Certain Conditions Originating in the Perinatal Period) state that, for coding and reporting purposes, the perinatal period is defined as before birth through the 28th day following birth. As such, for coding and reporting purposes, a patient that is beyond the 28th day of life is no longer considered a newborn. Therefore, we believe that the diagnosis codes listed on the newborn diagnosis category in the Age conflict edit code list are, in fact, appropriate because they identify what the title of Chapter 15 describes (certain conditions specific to beginning in the perinatal period); that is, a newborn. The intent of the diagnosis codes included on the Age conflict edit code list is to identify claims where any one of the listed diagnoses is reported for a patient who is beyond the 28th day of life. If that definition is met according to the patient's date of birth, the edit is correctly triggered in those cases.

Transitioning to the ICD–10 MCE was based on replication of the ICD–9–CM based MCE (in parallel with the transition to the ICD–10 MS–DRGs, which was based on replication of the ICD–9–CM MS–DRGs). Therefore, the diagnosis codes included in the newborn diagnosis category on the Age conflict edit code list in the ICD–10 MCE are a replication of the diagnosis code descriptions included on the newborn diagnosis category on the Age conflict edit code list under the ICD–9–CM MCE. However, the chapter-specific guideline in ICD–10–CM Chapter 16, section C.16.e. (Low birth weight and immaturity status), specifies that codes within category P07 (Disorders of newborn related to short gestation and low birth weight, not elsewhere classified) are for use for a child or adult who was premature or had a low birth weight as a newborn and this condition is affecting the patient's current health status. Therefore, we agree that codes within the range of P07.00 through P07.39 should not be listed under newborn diagnosis category on the Age conflict edit code list in the ICD–10 MCE. It is unclear why this range of codes within category P07 is distinguished separately when under the General Perinatal Rules for Chapter 16 (Certain Conditions Originating in the Perinatal Period), section I.C.16.a.1. states that diagnosis codes from Chapter 16 may be reported throughout the life of the patient if the condition is still present. In addition, the guideline at section I.C.16.a.4. states that "should a condition originate in the perinatal period, and continue throughout the life of the patient, the perinatal code should continue to be used regardless of the patient's age." According to these general guidelines, we could assume that potentially *all* codes within Chapter 16 in the code range of P00 through P96 should be considered for removal from the newborn diagnosis category on the Age conflict edit code list. However, a subsequent section of Chapter 16, section 1.C.16.c.2. (Codes for conditions specified as having implication for future health care needs), instructs users to assign codes for conditions that have been specified by the provider as having implications for future health care needs. Immediately below that instruction is a note which states: "This guideline should not be used for adult patients."

The ICD–10–CM Official Guidelines for Coding and Reporting are updated separately from the IPPS rulemaking process. Due to the confusion with the chapter-specific guidelines for codes in Chapter 16 and how they impact the newborn diagnosis category on the Age conflict edit code list, we believe it would be beneficial to fully evaluate the intent of these guidelines with the Centers for Disease Control's (CDC's) National Center for Health Statistics (NCHS) because NCHS has the lead responsibility for the ICD–10–CM diagnosis codes.

In the meantime, to address claims processing concerns related to the newborn diagnosis category on the Age conflict edit code list, we are proposing to remove all the ICD–10–CM diagnoses in the code range of P00 through P96 from the newborn diagnosis category in the Age conflict code edit list for the ICD–10 MCE for FY 2017. We are inviting public comments on our proposal. We also are soliciting public comments on the appropriateness of the other diagnosis codes currently listed under the newborn diagnosis category in the Age conflict edit in the ICD–10 MCE Version 33. We refer readers to Table 6P.1a. associated with this proposed rule (which is available via the Internet on the CMs Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) for review of the diagnosis codes we are proposing to remove. In addition, for FY 2017, we are examining the need to revise the description for the newborn diagnosis category in the Age conflict edit under the MCE. The current description as written, Newborn—Age of 0 years; a subset of diagnoses intended only for newborns and neonates (*e.g.*, fetal distress, perinatal jaundice), is not consistent with the instructions for reporting the diagnosis codes in Chapter 16. We are inviting public comments on our proposal to revise the description of the newborn diagnosis category in the Age conflict edit under the MCE.

(2) Pediatric Diagnosis Category

Under the ICD–10 MCE Version 33, the pediatric diagnosis category for the Age conflict edit considers the age range of 0 to 17 years inclusive. For that reason, the diagnosis codes on this Age conflict edit list would be expected to apply to conditions or disorders specific to that age group only. The code list for the pediatric diagnosis category in the Age conflict edit currently includes 12 diagnosis codes that fall within the F90 through F98 code range. These codes were included as a result of replication from the ICD–9–CM MCE Version 32 and the draft ICD–10 MCE Version 32.

We received a request to review the 12 ICD–10–CM diagnosis codes listed in the following table because they appear to conflict with guidance in the ICD–10–CM classification:

ICD–10–CM diagnosis code	Description
F93.0	Separation anxiety disorder of childhood.
F93.8	Other childhood emotional disorders.
F93.9	Childhood emotional disorder, unspecified.

ICD–10–CM diagnosis code	Description
F94.1	Reactive attachment disorder of childhood.
F94.2	Disinhibited attachment disorder of childhood.
F94.8	Other childhood disorders of social functioning.
F94.9	Childhood disorder of social functioning, unspecified.
F98.21	Rumination disorder of infancy.
F98.29	Other feeding disorders of infancy and early childhood.
F98.3	Pica of infancy and childhood.
F98.8	Other specified behavioral and emotional disorders with onset usually occurring in childhood and adolescence.
F98.9	Unspecified behavioral and emotional disorders with onset usually occurring in childhood and adolescence.

Under the ICD–10–CM Tabular List of Diseases and Injuries, Chapter 5 (Mental, Behavioral and Neurodevelopmental Disorders) contains a section titled "Behavioral and emotional disorders with onset usually occurring in childhood and adolescence" which includes codes for the F90 to F98 code range. At the beginning of this tabular section is an instructional "note" that states: "Codes within categories F90–F98 may be used regardless of the age of a patient. These disorders generally have onset within the childhood or adolescent years, but may continue throughout life or not be diagnosed until adulthood."

Because the note specifically states that these codes may be used regardless of the age of a patient, we believe they should not be included on the pediatric diagnosis category on the Age conflict edit code list. Therefore, we are proposing to remove the 12 codes that fall within the F90 through F98 code range currently listed for the pediatric diagnosis category on the ICD–10 MCE age conflict edit code list, effective October 1, 2016, for FY 2017. We are inviting public comments on our proposal.

We also received a request to review whether another group of diagnosis codes is clinically incorrect for the ICD–10 MCE Version 33 pediatric diagnosis category in the Age conflict edit. The requestor stated that ICD–10–CM diagnosis codes describing infantile and juvenile cataracts, by their titles, appear to merit inclusion on the pediatric diagnosis category on the Age conflict edit code list. However, according to the requestor, the diagnosis is not constrained to a patient's age, but rather the "infantile" versus "juvenile" reference is specific to the type of cataract the patient has. These diagnosis codes that are currently listed for the pediatric diagnosis category in the ICD–10 MCE Age conflict edit code list are as follows:

ICD–10–CM diagnosis code	Description
H26.001	Unspecified infantile and juvenile cataract, right eye.
H26.002	Unspecified infantile and juvenile cataract, left eye.
H26.003	Unspecified infantile and juvenile cataract, bilateral.
H26.009	Unspecified infantile and juvenile cataract, unspecified eye.
H26.011	Infantile and juvenile cortical, lamellar, or zonular cataract, right eye.
H26.012	Infantile and juvenile cortical, lamellar, or zonular cataract, left eye.
H26.013	Infantile and juvenile cortical, lamellar, or zonular cataract, bilateral.
H26.019	Infantile and juvenile cortical, lamellar, or zonular cataract, unspecified eye.
H26.031	Infantile and juvenile nuclear cataract, right eye.
H26.032	Infantile and juvenile nuclear cataract, left eye.
H26.033	Infantile and juvenile nuclear cataract, bilateral.
H26.039	Infantile and juvenile nuclear cataract, unspecified eye.
H26.041	Anterior subcapsular polar infantile and juvenile cataract, right eye.
H26.042	Anterior subcapsular polar infantile and juvenile cataract, left eye.
H26.043	Anterior subcapsular polar infantile and juvenile cataract, bilateral.
H26.049	Anterior subcapsular polar infantile and juvenile cataract, unspecified eye.
H26.051	Posterior subcapsular polar infantile and juvenile cataract, right eye.
H26.052	Posterior subcapsular polar infantile and juvenile cataract, left eye.
H26.053	Posterior subcapsular polar infantile and juvenile cataract, bilateral.
H26.059	Posterior subcapsular polar infantile and juvenile cataract, unspecified eye.
H26.061	Combined forms of infantile and juvenile cataract, right eye.
H26.062	Combined forms of infantile and juvenile cataract, left eye.
H26.063	Combined forms of infantile and juvenile cataract, bilateral.
H26.069	Combined forms of infantile and juvenile cataract, unspecified eye.
H26.09	Other infantile and juvenile cataract.

Our clinical advisors reviewed the list of diagnoses presented above and confirmed that these diagnosis codes are appropriate to include in the ICD–10 MCE for the pediatric diagnosis category in the Age conflict edit because the diseases described by these codes are typically diagnosed in early childhood and treated very rapidly to prevent amblyopia. Therefore, for FY 2017, we are not proposing to remove these codes under the pediatric diagnosis category in the Age conflict edit. We are proposing to maintain this list in the ICD–10 MCE Version 34, effective October 1, 2016. We are inviting public comments on our proposal.

As stated earlier, for the pediatric diagnosis category in the Age conflict edit, the MCE considers the age range of 0 through 17 years inclusive. In the ICD–10 MCE Version 33, there are four diagnosis codes describing the body mass index (BMI) for pediatric patients in the pediatric diagnosis category on the Age conflict edit code list. The four ICD–10–CM diagnosis codes describing the BMI percentiles for pediatric patients are as follows:

ICD–10–CM diagnosis code	Description
Z68.51	Body mass index (BMI) pediatric, less than 5th percentile for age.
Z68.52	Body mass index (BMI) pediatric, 5th percentile to less than 85th percentile for age.
Z68.53	Body mass index (BMI) pediatric, 85th percentile to less than 95th percentile for age.
Z68.54	Body mass index (BMI) pediatric, greater than or equal to 95th percentile for age.

Under the ICD–10–CM Tabular List of Diseases and Injuries, the BMI pediatric diagnosis codes are designated for use in persons 2 through 20 years of age. The percentiles are based on the growth charts published by the CDC. As a result of the age discrepancy between the MCE pediatric diagnosis category in the Age conflict edit (ages 0 through 17) and the Tabular reference for the BMI pediatric codes (ages 2 through 20), we are proposing to remove ICD–10 diagnosis codes Z68.51, Z68.52, Z68.53, and Z68.54 from the ICD–10 MCE pediatric diagnosis category on the Age conflict edit code list for Version 34, effective FY 2017. We are inviting public comments on our proposal.

One requestor also asked that CMS review the ICD–10–CM diagnosis codes currently included in ICD–10–CM category R62 (Lack of expected normal physiological development in childhood and adults) series. Specifically, the requestor noted that there are adult patients diagnosed with the conditions in subcategory R62.5 (Other and unspecified lack of expected normal physiological development in childhood) and that three of these conditions also were listed in the ICD–10 MCE Version 33 pediatric diagnosis category on the Age conflict edit code list. These three diagnosis codes are:

- R62.50 (Unspecified lack of expected normal physiological development in childhood);
- R62.52 (Short stature (child)); and
- R62.59 (Other lack of expected normal physiological development in childhood).

We acknowledge that subcategory R62.5 can be confusing with regard to how to appropriately report a condition diagnosed for an adult when the titles reference the terms "child" or "childhood". Therefore, we consulted with the ICD–10–CM classification staff at the NCHS to determine the intended use and reporting of the diagnosis codes R62.50, R62.52, and R62.59. The NCHS staff agreed that the three diagnosis codes should not be restricted to the pediatric ages as defined by the MCE. The NCHS staff stated the codes are appropriate to report for adult patients, noting that if a patient is diagnosed with short stature as a child, the patient could very well carry over that diagnosis into adulthood.

During our review of the issue relating to the subcategory R62.5 pediatric diagnosis category on the Age conflict edit code list, we identified another diagnosis code that also appeared appropriate to report for an adult patient. ICD–10–CM diagnosis code Y93.6A (Activity, physical games generally associated with school recess, summer camp and children) is one of several activity codes included in ICD–10–CM Chapter 20 (External Causes of Morbidity). This diagnosis code includes games such as dodge ball and captures the flag, which one can reasonably expect an adult to be engaged in for physical activity.

We discussed this diagnosis code with the NCHS staff to receive their input on the intent for coding and reporting the code. They agreed that ICD–10–CM diagnosis code Y93.6A is applicable for adults as well as children. Therefore, for FY 2017, we are proposing to remove ICD–10–CM diagnosis codes R62.50, R62.52, and R62.59 in subcategory R62.5 and ICD–10–CM diagnosis code Y93.6A from the ICD–10 MCE pediatric diagnosis category on the Age conflict edit code list. We are inviting public comment on our proposal.

b. Sex Conflict Edit

In the MCE, the Sex conflict edit detects inconsistencies between a patient's sex and any diagnosis or procedure on the patient's record; for example, a male patient with cervical cancer (diagnosis) or a female patient with a prostatectomy (procedure). In both instances, the indicated diagnosis or the procedure conflicts with the stated sex of the patient. Therefore, the patient's diagnosis, procedure, or sex is presumed to be incorrect.

We received a request to review ICD–10–CM diagnosis code Z79.890 (Hormone replacement therapy (postmenopausal)). This code is listed on the Diagnoses for females only edit code list. Therefore, when the diagnosis is reported for a male patient, the edit will be triggered. However, the requester noted that the term "postmenopausal" is enclosed in parentheses and is a "non-essential modifier." A "non-essential modifier" is used in the ICD–10–CM classification to identify a supplementary word that may, or may not be present in the statement of a disease or procedure. In other words, the term in parentheses does not have to be documented to report the code. If the medical record documentation states a female patient is undergoing hormone replacement therapy, the documentation supports assignment of the case to ICD–10–CM diagnosis code Z79.890 (Hormone replacement therapy (postmenopausal)). There does not need to be a diagnostic statement that the patient is postmenopausal to assign the code. The requester asked that CMS review why this diagnosis code is being classified as applicable to females only because, in the absence of the non-essential modifier (postmenopausal), the code could also apply to males.

We note that the ICD–9–CM equivalent code, V07.4 Hormone replacement therapy (postmenopausal) has been on the female only edit since October 1, 1992 in the ICD–9–CM MCE. We consulted with the ICD–10–CM classification staff at the NCHS to determine the intended use and reporting of this diagnosis code. The staff at NCHS acknowledged that, historically, the intent of the ICD–9–CM diagnosis code was for females only. However, they agreed that, under ICD–10–CM, the diagnosis code Z79.890 can be reported for both men and women. Therefore, we are proposing to remove this diagnosis code from the Diagnoses for females only edit code list effective October 1, 2016. We are inviting public comments on our proposal.

We also considered the ICD–10–CM diagnosis codes listed in the table below that are included on the Diagnoses for females only edit code list.

ICD–10–CM diagnosis code	Description
Z44.30	Encounter for fitting and adjustment of external breast prosthesis, unspecified breast.
Z44.31	Encounter for fitting and adjustment of external right breast prosthesis.
Z44.32	Encounter for fitting and adjustment of external left breast prosthesis).
Z45.811	Encounter for adjustment or removal of right breast implant.
Z45.812	Encounter for adjustment or removal of left breast implant.
Z45.819	Encounter for adjustment or removal of unspecified breast implant).

These codes describe encounters for breast implants or prostheses. Our clinical advisors and the NCHS staff agree that diagnosis codes Z44.30, Z44.31, Z44.32, Z45.811, Z45.812, and Z45.819 are clinically appropriate to report for male patients and should not be restricted to females. Therefore, we are proposing to remove these diagnosis codes from the Diagnoses for females only edit code list in the ICD–10 MCE, effective October 1, 2016. We are inviting public comments on our proposal.

c. Non-Covered Procedure Edit

In the MCE, the Non-covered procedure edit identifies procedures for which Medicare does not provide payment. Payment is not provided due to specific criteria that are established in the National Coverage Determination (NCD) process. We refer readers to the Web site at: ***https://www.cms.gov/Medicare/Coverage/DeterminationProcess/*** *howtorequestanNCD.html* for additional information on this process. In addition, there are procedures that would normally not be paid by Medicare but, due to the presence of certain diagnoses, are paid.

(1) Endovascular Mechanical Thrombectomy

We received several requests to review ICD–10–PCS procedure code 03CG3ZZ (Extirpation of matter from intracranial artery, percutaneous approach) which is currently listed as a non-covered procedure in the ICD–10 MCE Non-covered procedure edit code list. The comparable ICD–9–CM code translations for ICD–10–PCS code 03CG3ZZ are ICD–9–CM codes 17.54 (Percutaneous atherectomy of intracranial vessel(s)) and 39.74 (Endovascular removal of obstruction from head and neck vessel(s)).

The requestors noted that, under ICD–9–CM, endovascular mechanical thrombectomy of a cerebral artery to remove a clot that is causing an ischemic stroke was reported with procedure code 39.74 (Endovascular removal of obstruction from head and neck vessel(s)) and is a well-recognized procedure that has been covered by Medicare. After implementation of ICD–10 on October 1, 2015, claims that were correctly submitted for endovascular mechanical thrombectomy procedures with ICD–10–PCS procedure code 03CG3ZZ were triggering the Non-covered procedure edit. The requestors sought clarification as to whether there was a change in coverage or if there was a replication issue.

Under the ICD–9–CM MCE Version 32, procedure code 00.62 is listed on the Non-covered procedure edit code list. Percutaneous angioplasty of an intracranial vessel procedure (with and without stent) may be reported under ICD–10 with the ICD–10–PCS procedure codes listed in the following table:

ICD–10–PCS procedure code	Description
037G34Z	Dilation of intracranial artery with drug-eluting intraluminal device, percutaneous approach.
037G3DZ	Dilation of intracranial artery with intraluminal device, percutaneous approach.
037G3ZZ	Dilation of intracranial artery, percutaneous approach.
037G44Z	Dilation of intracranial artery with drug-eluting intraluminal device, percutaneous endoscopic approach.
037G4DZ	Dilation of intracranial artery with intraluminal device, percutaneous endoscopic approach.
037G4ZZ	Dilation of intracranial artery, percutaneous endoscopic approach.
057L3DZ	Dilation of intracranial vein with intraluminal device, percutaneous approach.
057L4DZ	Dilation of intracranial vein with intraluminal device, percutaneous endoscopic approach.

We discovered that a replication error occurred due to an outdated ICD–9–CM entry for procedure code 00.62. This error led to ICD–10–PCS procedure codes 03CG3ZZ (Extirpation of matter from intracranial artery, percutaneous approach) and 05CL3ZZ (Extirpation of matter from intracranial vein, percutaneous approach) being listed as comparable translations for ICD–9–CM code 00.62. As a result, ICD–10–PCS procedure code 03CG3ZZ was included on the ICD–10 MCE Version 33 Non-covered procedure edit code list.

For FY 2017, we are proposing to remove the ICD–10–PCS procedure codes listed in the following table from the ICD–10 MCE Version 34.0 Non-covered procedure edit code list.

ICD–10–PCS procedure code	Description
03CG3ZZ	Extirpation of matter from intracranial artery, percutaneous approach.
03CG4ZZ	Extirpation of matter from intracranial artery, percutaneous endoscopic approach.
05CL3ZZ	Extirpation of matter from intracranial vein, percutaneous approach.
05CL4ZZ	Extirpation of matter from intracranial vein, percutaneous endoscopic approach.

We are inviting public comments on our proposal.

(2) Radical Prostatectomy

We received a request to review ICD–10–PCS procedure codes related to a radical prostatectomy. Specifically, the requestor noted that when coding cases where the removal of the vas deferens is also performed, a Non-covered procedure edit is triggered. The requestor suggested that the edit for this procedure may be intended for cases where the removal of the vas deferens is being performed for sterilization (vasectomy) purposes. According to the requester, removal of the vas deferens also may be involved with removing the prostate in the radical prostatectomy procedure. The requestor suggested that CMS address this issue by revising the ICD–10 MCE Non-covered procedure edit code list to reflect non-coverage of the procedure codes when the removal of vas deferens procedure is being performed solely for sterilization (vasectomy) purposes.

Because radical procedures can have different meanings, depending on the procedure, the term "radical" is not always reliable information for coding and reporting the procedure. Under ICD–10–PCS, users are instructed to code separately the organs or structures that were actually removed and for which there is a distinctly defined body part. A radical prostatectomy is coded as a "cluster" under ICD–10–PCS. A "cluster" is the term used to describe the circumstance when a combination of ICD–10–PCS procedure codes are needed to fully satisfy the equivalent meaning of an ICD–9–CM procedure code for it to be considered a plausible translation.

The cluster definition for a radical prostatectomy in ICD–10–PCS currently consists of the one of the following codes:

- 0VT00ZZ (Resection of prostate, open approach);
- 0VT04ZZ (Resection of prostate, percutaneous endoscopic approach);
- 0VT07ZZ (Resection of prostate, via natural or artificial opening); or
- 0VT08ZZ Resection of prostate, via natural or artificial opening endoscopic; in combination with one of the following codes:
- 0VT30ZZ (Resection of bilateral seminal vesicles, open approach); or
- 0VT34ZZ (Resection of bilateral seminal vesicles, percutaneous endoscopic approach).

As stated earlier, under ICD–10–PCS, users are instructed to code separately the organs or structures that were actually removed and for which there is a distinctly defined body part. Therefore, a patient who undergoes a radical prostatectomy that involves removal of the vas deferens would have this procedure reported separately, in addition to the options displayed in the "cluster."

The ICD–10–PCS procedure codes that may be reported for sterilization and involve the bilateral vas deferens include the following:

ICD–10–PCS procedure code	Description
0V5Q0ZZ	Destruction of bilateral vas deferens, open approach.
0V5Q3ZZ	Destruction of bilateral vas deferens, percutaneous approach.
0V5Q4ZZ	Destruction of bilateral vas deferens, percutaneous endoscopic approach.
0VBQ0ZZ	Excision of bilateral vas deferens, open approach.
0VBQ3ZZ	Excision of bilateral vas deferens, percutaneous approach.
0VBQ4ZZ	Excision of bilateral vas deferens, percutaneous endoscopic approach.
0VTQ0ZZ	Resection of bilateral vas deferens, open approach.
0VTQ4ZZ	Resection of bilateral vas deferens, percutaneous endoscopic approach.

The eight procedure codes listed above describing various methods to remove the bilateral vas deferens are currently listed on the ICD–10 MCE Version 33 Non-covered procedure edit code list.

The requester is correct in stating that the codes related to removal of the bilateral vas deferens are included on the ICD–10 MCE Version 33 Non-covered procedure edit code list to reflect a sterilization procedure. While the vast majority of sterilization procedures will involve reporting the bilateral procedure codes, there are instances where one vas deferens may have been previously removed for other reasons and the remaining vas deferens requires sterilization. Therefore, the procedure codes describing removal of a unilateral vas deferens are also included on the ICD–10 MCE Version 33 Non-covered procedure edit code list to reflect a sterilization procedure. We agree that revising the language in the edit will resolve the issue of covered procedures being inappropriately subject to the edit.

In addition, while reviewing the Non-covered procedure edit list of codes that may be reported to identify sterilization procedures for males, we considered the procedure codes that may be reported to identify sterilization procedures for females. We examined the list of ICD–10–PCS procedure codes included on the ICD–10 MCE Version 33 Non-covered procedure edit code list that could reflect female sterilization (removal of fallopian tubes) and determined those codes also could be reported for other conditions and could be inappropriately subject to the current edit as well.

Therefore, for FY 2017, we are proposing to create a new ICD–10 MCE Version 34 Non-covered procedure edit to reflect that procedures performed on males involving the unilateral or bilateral vas deferens and procedures performed on females involving the fallopian tubes are not covered procedures for sterilization purposes. The proposed new ICD–10 MCE Version 34 Non-covered procedure edit would be displayed as follows: "G. Non-covered procedure. The procedure codes shown below are identified as non-covered procedures *only* when ICD–10–CM diagnosis code Z30.2 (Encounter for sterilization) is listed as the principal diagnosis."

We refer readers to Table 6P.1b. associated with this proposed rule (which are available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) to review the proposed list of non-covered procedure codes describing sterilization procedures for males and females for this proposed Non-covered procedure edit. We are inviting public comments on our proposal to create this new Non-covered procedure edit and also invite public comments on the proposed list of codes to describe sterilization procedures for the proposed edit.

d. Unacceptable Principal Diagnosis Edit

In the MCE, there are select codes that describe a circumstance which influences an individual's health status but does not actually describe a current illness or injury. There also are codes that are not specific manifestations but may be due to an underlying cause. These codes are considered unacceptable as a principal diagnosis. In limited situations, there are a few codes on the MCE Unacceptable principal diagnosis edit code list that are considered "acceptable" when a specified secondary diagnosis is also coded and reported on the claim.

(1) Liveborn Infant

We received a request to examine ICD–10–CM diagnosis codes Z38.1 (Single liveborn infant, born outside hospital), Z38.4 (Twin liveborn infant, born outside hospital), and Z38.7 (Other multiple liveborn infant, born outside hospital), all of which are currently listed on the Unacceptable principal diagnosis edit code list for the ICD–10 MCE Version 33. The requestor believed that these codes are listed in error and suggested their removal.

The ICD–10–CM diagnosis code descriptions for liveborn infants differ from the ICD–9–CM diagnosis code descriptions for liveborn infants. The ICD–9–CM codes differentiate between a liveborn infant that was born prior to admission and hospitalized versus a liveborn infant that was born prior to admission and *not* hospitalized. The following codes in the ICD–9–CM MCE Version 32 included on the Unacceptable principal diagnosis edit code list are those that describe a liveborn infant that was born outside the hospital and not hospitalized:

ICD–9–CM diagnosis code	Description
V30.2	Single liveborn, born outside hospital and not hospitalized.
V31.2	Twin birth, mate liveborn, born outside hospital and not hospitalized.
V32.2	Twin birth, mate stillborn, born outside hospital and not hospitalized.
V33.2	Twin birth, unspecified whether mate liveborn or stillborn, born outside hospital and not hospitalized.
V34.2	Other multiple birth (three or more), mates all liveborn, born outside hospital and not hospitalized.
V35.2	Other multiple birth (three or more), mates all stillborn, born outside of hospital and not hospitalized.
V36.2	Other multiple birth (three or more), mates liveborn and stillborn, born outside hospital and not hospitalized.
V37.2	Other multiple birth (three or more), unspecified whether mates liveborn or stillborn, born outside of hospital.
V39.1	Liveborn, unspecified whether single, twin or multiple, born before admission to hospital.
V39.2	Liveborn, unspecified whether single, twin or multiple, born outside hospital and not hospitalized.

For replication purposes, the comparable ICD–10–CM diagnosis codes for the above listed codes are: Z38.1 (Single liveborn infant, born outside hospital); Z38.4 (Twin liveborn infant, born outside hospital); and Z38.7 (Other multiple liveborn infant, born outside hospital). There are no other ICD–10–CM diagnosis codes that describe a liveborn infant born outside a hospital.

The liveborn infant codes are an example of where a particular concept involving the place of birth is not the same between the ICD–9–CM and ICD–10–CM classification systems. Because the ICD–10–CM diagnosis codes do not include the same concept as the ICD–9–CM diagnosis codes regarding whether the liveborn infant was hospitalized or not, we agree it would not be appropriate to continue to include the ICD–10–CM diagnosis codes on the Unacceptable principal diagnosis list.

For FY 2017, we are proposing to remove ICD–10–CM diagnosis codes Z38.1, Z38.4, and Z38.7 from the Unacceptable principal diagnosis edit in the ICD–10 MCE Version 34. We are inviting public comments on our proposal.

(2) Multiple Gestation

We received a request to review the ICD–10–CM diagnosis codes related to multiple gestation that are currently listed on the ICD–10 MCE Version 33 Unacceptable principal diagnosis edit code list. The requestor expressed concern that these codes were included in the edit and suggested that CMS evaluate further to determine if they were appropriate.

In the ICD–10–CM classification, a single diagnosis code describes a multiple gestation and contains information pertaining to the placenta. This differs from the ICD–9–CM classification, where two diagnosis codes are required to separately report (1) multiple gestation with a delivery or complication and (2) multiple gestation with the status of the placenta.

In the ICD–9–CM MCE Version 32, only the ICD–9–CM diagnosis codes describing the status of the placenta are listed on the Unacceptable principal diagnosis edit code list. These ICD–9–CM diagnosis codes are:

ICD–9–CM diagnosis code	Description
V91.00	Twin gestation, unspecified number of placenta, unspecified number of amniotic sacs.
V91.01	Twin gestation, monochorionic/monoamniotic (one placenta, one amniotic sac).
V91.02	Twin gestation, monochorionic/diamniotic (one placenta, two amniotic sacs).
V91.03	Twin gestation, dichorionic/diamniotic (two placentae, two amniotic sacs).
V91.09	Twin gestation, unable to determine number of placenta and number of amniotic sacs.
V91.10	Triplet gestation, unspecified number of placenta and unspecified number of amniotic sacs.
V91.11	Triplet gestation, with two or more monochorionic fetuses.
V91.12	Triplet gestation, with two or more monoamniotic fetuses.
V91.19	Triplet gestation, unable to determine number of placenta and number of amniotic sacs.
V91.20	(Quadruplet gestation, unspecified number of placenta and unspecified number of amniotic sacs.
V91.21	Quadruplet gestation, with two or more monochorionic fetuses.
V91.22	Quadruplet gestation, with two or more monoamniotic fetuses.
V91.29	Quadruplet gestation, unable to determine number of placenta and number of amniotic sacs.
V91.90	Other specified multiple gestation, unspecified number of placenta and unspecified number of amniotic sacs.
V91.91	Other specified multiple gestation, with two or more monochorionic fetuses.
V91.92	Other specified multiple gestation, with two or more monoamniotic fetuses.

ICD–9–CM diagnosis code	Description
V91.99	Other specified multiple gestation, unable to determine number of placenta and number of amniotic sacs.

There are 68 ICD–10–CM diagnosis codes included on the ICD–10 MCE Version 33 Unacceptable principal diagnosis edit code list as comparable translations that describe multiple gestation and status of the placenta. The list of these codes is included in Table 6P.1c. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*).

Because only one, and not both, concepts from the ICD–9–CM classification was considered to be an unacceptable principal diagnosis (status of placenta) in the ICD–9–CM MCE, we agree this was a replication error that incorrectly included the ICD–10–CM diagnosis codes that identify both concepts (multiple gestation and status of placenta) in a single code on the ICD–10 MCE. The edit cannot isolate the status of placenta for the ICD–10 MCE because it is reported in combination with the multiple gestation as a single code. Therefore, it is inappropriate to include these codes on the Unacceptable principal diagnosis edit code list.

For FY 2017, we are proposing to remove the ICD–10–CM diagnosis codes listed in Table 6P.1c. associated with this proposed rule (which is available via Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) from the ICD–10 MCE Version 34 Unacceptable principal diagnosis list. We are inviting public comments on our proposal.

(3) Supervision of High Risk Pregnancy

We received a request to review the ICD–10–CM diagnosis codes related to supervision of high risk pregnancy (elderly primigravida and multigravida) that are currently listed on the ICD–10 MCE Version 33 Unacceptable principal diagnosis edit code list. The requestor stated that these codes were not included in the edit under the ICD–9–CM MCE. According to the requester, the codes describing these conditions should be allowed for reporting as a principal diagnosis based on the ICD–10–CM Tabular List of Diseases instructions for Chapter 15 (Certain Conditions Originating in the Perinatal Period). The chapter-specific guidelines for ICD–10–CM state that "diagnosis code O80 (Encounter for full-term uncomplicated delivery) should be assigned when a woman is admitted for a full-term normal delivery and delivers a single, healthy infant without any complications antepartum, during the delivery, or postpartum during the delivery episode. Code O80 is always a principal diagnosis. It is not to be used if any other code from Chapter 15 is needed to describe a current complication of the antenatal, delivery, or perinatal period." The requestor stated that obstetric patients admitted as inpatients often meet the definition of an elderly primigravida or elderly multigravida,[1] which is the appropriate condition to be reported as the principal diagnosis. However, because the codes describing this condition are listed on the Unacceptable principal diagnosis edit code list, they are unable to be reported.

The diagnosis codes describing high-risk patients admitted for delivery differ between the ICD–10–CM and ICD–9–CM classifications. Under ICD–9–CM, two diagnosis codes are required to separately report concept 1 of elderly primigravida or elderly multigravida and whether a delivery occurred and concept 2 of supervision of high-risk pregnancy with elderly primigravida or elderly multigravida. We display the codes that correspond to these concepts below and titled them as Code List 1 and Code List 2. A code from each list would be reported to fully describe the circumstances of the admission and the patient.

Code List 1—We note that the following codes are listed on the ICD–9–CM MCE Version 32 Unacceptable principal diagnosis edit code list:

ICD–9–CM diagnosis code	Description
V23.81	Supervision of high-risk pregnancy with elderly primigravida
V23.82	Supervision of high-risk pregnancy with elderly multigravida

Code List 2—We note that the following codes are *not* listed on the ICD–9–CM MCE Version 32 Unacceptable principal diagnosis edit code list. However, we display them here for the benefit of the reader in the discussion that follows.

ICD–9–CM diagnosis code	Description
659.50	Elderly primigravida, unspecified as to episode of care or not applicable
659.51	Elderly primigravida, delivered, with or without mention of antepartum condition
659.53	Elderly primigravida, antepartum condition or complication
659.60	Elderly multigravida, unspecified as to episode of care or not applicable
659.61	Elderly multigravida, delivered with or without mention of antepartum condition
659.63	Elderly multigravida, antepartum condition or complication

As noted above, in the ICD–9–CM MCE Version 32, only the ICD–9–CM diagnosis codes describing the supervision of high-risk pregnancy are listed on the Unacceptable principal diagnosis edit code list.

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[1] The ICD–10–CM classification defines an elderly primigravida or elderly multigravida as a complication of the pregnancy since the management and care of the expectant mother is affected by the fact they are an older patient.

There are eight ICD–10–CM diagnosis codes included on the ICD–10 MCE Version 33 Unacceptable principal diagnosis edit code list that describe the concept of elderly primigravida or elderly multigravida and supervision of high-risk pregnancy, in a *single* code. As shown below, the concept of whether a delivery occurred is not included in the code description for the eight codes.

ICD–10–CM diagnosis code	Description
O09.511	Supervision of elderly primigravida, first trimester
O09.512	Supervision of elderly primigravida, second trimester
O09.513	Supervision of elderly primigravida, third trimester
O09.519	Supervision of elderly primigravida, unspecified trimester
O09.521	Supervision of elderly multigravida, first trimester
O09.522	Supervision of elderly multigravida, second trimester
O09.523	Supervision of elderly multigravida, third trimester
O09.529	Supervision of elderly multigravida, unspecified trimester

Because the concepts and coding guidelines between the ICD–9–CM and ICD–10–CM classifications differ greatly in how they define this subset of patients, we acknowledge that the eight ICD–10–CM diagnosis codes listed above should be removed from the ICD–10 MCE Unacceptable principal diagnosis edit code list to permit the reporting of these codes as principal diagnosis when the documentation supports such assignment.

We also note that during our analysis of the eight diagnosis codes describing elderly primigravida and elderly multigravida high risk pregnancy patients, we found additional codes on the ICD–10 MCE Version 33 Unacceptable principal diagnosis edit code list related to high-risk pregnancy that we believe should also be removed so as to permit the reporting of these codes as principal diagnosis when the documentation supports such assignment.

For FY 2017, we are proposing to remove all the ICD–10–CM diagnosis codes related to high-risk pregnancy currently listed in Table 6P.1d. associated with this proposed rule (which is available via Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) from the ICD–10 MCE Version 34 Unacceptable principal diagnosis edit code list. We are inviting public comment on our proposal.

e. Other MCE Issues

The following MCE discussion and proposals are the result of internal review of other MCE issues.

(1) Procedure Inconsistent With Length of Stay Edit

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49411), we finalized a revision for the language of the ICD–10 MCE Version 33 edit for "Procedure inconsistent with length of stay" with regard to ICD–10–PCS procedure code 5A1955Z (Respiratory ventilation, greater than 96 consecutive hours). The current description of the code edit reads as follows: "The following procedure code should only be coded on claims with a length of stay greater than four days."

As we strive to assist providers with correct coding and reporting of this service, we are proposing to further revise the description of this code edit. For FY 2017, we are proposing to modify the edit description to read as follows: "The following procedure code should only be coded on claims when the respiratory ventilation is provided for greater than four consecutive days during the length of stay."

We believe this modification will further clarify the appropriate circumstances in which ICD–10–PCS code 5A1955Z may be reported. We are inviting public comments on our proposal.

Also, consistent with the discussion in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49411 through 49412), we believe it would be beneficial to revise the title for ICD–10 MS–DRG 208 (Respiratory System Diagnosis with Ventilator Support <96 Hours). Currently, this ICD–10 MS–DRG title references terminology for mechanical ventilation "< 96 hours" based on the GROUPER logic for MS–DRG 208, which includes ICD–10–PCS codes 5A1935Z (Respiratory ventilation, less than 24 consecutive hours) and 5A1945Z (Respiratory ventilation, 24–96 consecutive hours). Because ICD–10–PCS code 5A1945Z includes mechanical ventilation up to and including 96 hours, we are proposing to modify the title of MS–DRG 208 by adding an "equal" sign (=) after the "less than" (<) sign to better reflect the GROUPER logic. We are proposing to revise the title of ICD–10 MS–DRG 208 as follows, effective October 1, 2016: MS–DRG 208 (Respiratory System Diagnosis with Ventilator Support <=96 Hours). We are inviting public comments on our proposal.

(2) Maternity Diagnoses

We identified three ICD–10–CM diagnosis codes that describe conditions related to pregnancy or the puerperium that are not currently listed on the ICD–10 MCE Version 33 Age conflict edit code list for maternity diagnoses. The diagnosis codes include:

- C58 (Malignant neoplasm of placenta);
- D39.2 (Neoplasm of uncertain behavior of placenta); and
- F53 (Puerperal psychosis).

To be consistent with other related conditions currently included on the Age conflict edit code list for maternity diagnoses, we are proposing to add ICD–10–CM diagnosis codes C58, D39.2, and F53 to the Age conflict edit code list for maternity diagnoses.

We are inviting public comments on our proposals for changes to the FY 2017 ICD–10 MCE Version 34.

(3) Manifestation Codes Not Allowed as Principal Diagnosis Edit

Section I.A.13. of the FY 2016 ICD–10–CM Official Guidelines for Coding and Reporting states that certain conditions have both an underlying etiology and multiple body system manifestations due to the underlying etiology. For such conditions, the classification has a coding convention that requires the underlying condition be sequenced first followed by the manifestation. Wherever such a combination exists, there is a "use additional code" note at the etiology code, and a "code first" note at the manifestation code. These instructional notes indicate proper sequencing order of the codes, etiology followed by manifestation.

We found that in the ICD–10–CM Tabular List of Diseases at category M02- (Postinfective and reactive arthropathies), a "Code first underlying disease" note exists. This would indicate that there are codes in that category that are manifestations of an underlying etiology. We then examined the ICD–10 MCE Version 33 to determine if diagnosis codes from that category were included on the Manifestation codes not allowed as principal diagnosis edit code list. Only three ICD–10–CM diagnosis codes from that category were listed:

- M02.88 (Other reactive arthropathies, vertebrae);
- M02.89 (Other reactive arthropathies, multiple sites); and
- M02.9 (Reactive arthropathy, unspecified).

Based on the instructional note at the M02- category level, the title at subcategory M02.8 (Other reactive arthropathies), and the three diagnosis codes listed above on the current ICD–10 MCE Version 33 Manifestation codes not allowed as principal diagnosis edit code list, it seems appropriate that all of the diagnosis codes in subcategory M02.8 should be identified as manifestation codes.

We are proposing to add the ICD–10–CM diagnosis codes listed in the following table to the ICD–10 MCE Version 34 Manifestation codes not allowed as principal diagnosis edit code list.

ICD–10–CM diagnosis code	Description
M02.80	Other reactive arthropathies, unspecified site.
M02.811	Other reactive arthropathies, right shoulder.
M02.812	Other reactive arthropathies, left shoulder.
M02.819	Other reactive arthropathies, unspecified shoulder.
M02.821	Other reactive arthropathies, right elbow.
M02.822	Other reactive arthropathies, left elbow.
M02.829	Other reactive arthropathies, unspecified elbow.
M02.831	Other reactive arthropathies, right wrist.
M02.832	Other reactive arthropathies, left wrist.
M02.839	Other reactive arthropathies, unspecified wrist.
M02.841	Other reactive arthropathies, right hand.
M02.842	Other reactive arthropathies, left hand.
M02.849	Other reactive arthropathies, unspecified hand.
M02.851	Other reactive arthropathies, right hip.
M02.852	Other reactive arthropathies, left hip.
M02.859	Other reactive arthropathies, unspecified hip.
M02.861	Other reactive arthropathies, right knee.
M02.862	Other reactive arthropathies, left knee.
M02.869	Other reactive arthropathies, unspecified knee.
M02.871	Other reactive arthropathies, right ankle and foot.
M02.872	Other reactive arthropathies, left ankle and foot.
M02.879	Other reactive arthropathies, unspecified ankle and foot.

We are inviting public comments on our proposal.

(4) Questionable Admission Edit

In the MCE, some diagnoses are not usually sufficient justification for admission to an acute care hospital. For example, if a patient is assigned ICD–10–CM diagnosis code R03.0 (Elevated blood pressure reading, without diagnosis of hypertension), the patient would have a questionable admission because an elevated blood pressure reading is not normally sufficient justification for admission to a hospital.

Upon review of the ICD–10–CM diagnosis codes listed under the ICD–10 MCE Version 33 Questionable Admission edit, our clinical advisors determined that certain diagnoses clinically warrant hospital admission. Therefore, we are proposing to remove the following diagnosis codes from the ICD–10 MCE Version 34.0 Questionable admission edit.

- T81.81XA (Complication of inhalation therapy, initial encounter);
- T88.4XXA (Failed or difficult intubation, initial encounter);
- T88.7XXA (Unspecified adverse effect of drug or medicament, initial encounter);
- T88.8XXA (Other specified complications of surgical and medical care, not elsewhere classified, initial encounter); and
- T88.9XXA (Complication of surgical and medical care, unspecified, initial encounter).

We are inviting public comments on our proposal.

(5) Removal of Edits and Future Enhancement

With the implementation of ICD–10, it is clear that there are several concepts that differ from the ICD–9–CM classification. These differences are evident in the MCE as discussed earlier in this section. Looking ahead to the needs and uses of coded data as the data continue to evolve from the reporting, collection, processing, coverage, payment and analysis aspect, we believe the need to ensure the accuracy of the coded data becomes increasingly significant.

The purpose of the MCE is to ensure that errors and inconsistencies in the coded data are recognized during Medicare claims processing. As shown in the FY 2016 ICD–10 MCE Version 33 manual file and an ICD–9–CM MCE Version 33.0A manual file (developed for analysis only), an edit code list exists according to the definition or criteria set forth for each specified type of edit. Over time, certain edits under the ICD–9–CM MCE became discontinued as they were no longer needed. However, the MCE manual has continued to make reference to these discontinued edits, including through the replication process with transitioning to ICD–10.

Currently, the FY 2016 ICD–10 MCE Version 33 manual file displays the following edits:

- 12. Open biopsy check. Effective October 1, 2010, the Open biopsy check edit was discontinued and will appear for claims processed using MCE Version 2.0–26.0 only.
- 13. Bilateral procedure. Effective with the ICD–10 implementation, the bilateral procedure edit will be discontinued.

Because these edits are no longer valid, we are proposing to remove the reference to them, effective with the ICD–10 MCE manual and software

Version 34.0, for FY 2017. We are inviting public comments on our proposal.

As we continue to evaluate the purpose and function of the MCE with respect to the transition to ICD–10, we encourage public input for future discussion. For instance, we recognize a need to further examine the current list of edits and the definitions of those edits. We encourage public comments on whether there are additional concerns with the current edits, including specific edits or language that should be removed or revised, edits that should be combined, or new edits that should be added to assist in detecting errors or inaccuracies in the coded data.

13. Proposed Changes to Surgical Hierarchies

Some inpatient stays entail multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different MS–DRG within the MDC to which the principal diagnosis is assigned. Therefore, it is necessary to have a decision rule within the GROUPER by which these cases are assigned to a single MS–DRG. The surgical hierarchy, an ordering of surgical classes from most resource-intensive to least resource-intensive, performs that function. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the MS–DRG associated with the most resource-intensive surgical class.

Because the relative resource intensity of surgical classes can shift as a function of MS–DRG reclassification and recalibrations, for FY 2017, we reviewed the surgical hierarchy of each MDC, as we have for previous reclassifications and recalibrations, to determine if the ordering of classes coincides with the intensity of resource utilization.

A surgical class can be composed of one or more MS–DRGs. For example, in MDC 11, the surgical class "kidney transplant" consists of a single MS–DRG (MS–DRG 652) and the class "major bladder procedures" consists of three MS–DRGs (MS–DRGs 653, 654, and 655). Consequently, in many cases, the surgical hierarchy has an impact on more than one MS–DRG. The methodology for determining the most resource-intensive surgical class involves weighting the average resources for each MS–DRG by frequency to determine the weighted average resources for each surgical class. For example, assume surgical class A includes MS–DRGs 001 and 002 and surgical class B includes MS–DRGs 003, 004, and 005. Assume also that the average costs of MS–DRG 001 are higher than that of MS–DRG 003, but the average costs of MS–DRGs 004 and 005 are higher than the average costs of MS–DRG 002. To determine whether surgical class A should be higher or lower than surgical class B in the surgical hierarchy, we would weigh the average costs of each MS–DRG in the class by frequency (that is, by the number of cases in the MS–DRG) to determine average resource consumption for the surgical class. The surgical classes would then be ordered from the class with the highest average resource utilization to that with the lowest, with the exception of "other O.R. procedures" as discussed in this rule.

This methodology may occasionally result in assignment of a case involving multiple procedures to the lower-weighted MS–DRG (in the highest, most resource-intensive surgical class) of the available alternatives. However, given that the logic underlying the surgical hierarchy provides that the GROUPER search for the procedure in the most resource-intensive surgical class, in cases involving multiple procedures, this result is sometimes unavoidable.

We note that, notwithstanding the foregoing discussion, there are a few instances when a surgical class with a lower average cost is ordered above a surgical class with a higher average cost. For example, the "other O.R. procedures" surgical class is uniformly ordered last in the surgical hierarchy of each MDC in which it occurs, regardless of the fact that the average costs for the MS–DRG or MS–DRGs in that surgical class may be higher than those for other surgical classes in the MDC. The "other O.R. procedures" class is a group of procedures that are only infrequently related to the diagnoses in the MDC, but are still occasionally performed on patients with cases assigned to the MDC with these diagnoses. Therefore, assignment to these surgical classes should only occur if no other surgical class more closely related to the diagnoses in the MDC is appropriate.

A second example occurs when the difference between the average costs for two surgical classes is very small. We have found that small differences generally do not warrant reordering of the hierarchy because, as a result of reassigning cases on the basis of the hierarchy change, the average costs are likely to shift such that the higher-ordered surgical class has lower average costs than the class ordered below it.

Based on the changes that we are proposing to make for FY 2017, as discussed in section II.F.4.c. of the preamble of this FY 2017 IPPS/LTCH PPS proposed rule, we are proposing to maintain the existing surgical hierarchy in MDC 5 for proposed revised MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with MCC and without MCC, respectively).

We are inviting public comments on our proposals.

14. Proposed Changes to the MS–DRG Diagnosis Codes for FY 2017

The tables identifying the proposed additions and deletions to the MCC severity levels list and the proposed additions and deletions to the CC severity levels list for FY 2017 are available via the Internet on the CMS Web site at: *http://cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* as follows:

- Table 6I.1—Proposed Additions to the MCC List—FY 2017;
- Table 6I.2—Proposed Deletions to the MCC List—FY 2017;
- Table 6J.1—Proposed Additions to the CC List—FY 2017; and
- Table 6J.2—Proposed Deletions to the CC List—FY 2017.

15. Proposed Complications or Comorbidity (CC) Exclusions List

a. Background of the CC List and the CC Exclusions List

Under the IPPS MS–DRG classification system, we have developed a standard list of diagnoses that are considered CCs. Historically, we developed this list using physician panels that classified each diagnosis code based on whether the diagnosis, when present as a secondary condition, would be considered a substantial complication or comorbidity. A substantial complication or comorbidity was defined as a condition that, because of its presence with a specific principal diagnosis, would cause an increase in the length of stay by at least 1 day in at least 75 percent of the patients. However, depending on the principal diagnosis of the patient, some diagnoses on the basic list of complications and comorbidities may be excluded if they are closely related to the principal diagnosis. In FY 2008, we evaluated each diagnosis code to determine its impact on resource use and to determine the most appropriate CC subclassification (non-CC, CC, or MCC) assignment. We refer readers to sections II.D.2. and 3. of the preamble of the FY 2008 IPPS final rule with comment period for a discussion of the refinement of CCs in relation to the MS–DRGs we adopted for FY 2008 (72 FR 47152 through 47171).

b. Proposed CC Exclusions List for FY 2017

In the September 1, 1987 final notice (52 FR 33143) concerning changes to the DRG classification system, we modified the GROUPER logic so that certain diagnoses included on the standard list of CCs would not be considered valid CCs in combination with a particular principal diagnosis. We created the CC Exclusions List for the following reasons: (1) To preclude coding of CCs for closely related conditions; (2) to preclude duplicative or inconsistent coding from being treated as CCs; and (3) to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair. As previously indicated, we developed a list of diagnoses, using physician panels, to include those diagnoses that, when present as a secondary condition, would be considered a substantial complication or comorbidity. In previous years, we made changes to the list of CCs, either by adding new CCs or deleting CCs already on the list.

In the May 19, 1987 proposed notice (52 FR 18877) and the September 1, 1987 final notice (52 FR 33154), we explained that the excluded secondary diagnoses were established using the following five principles:

- Chronic and acute manifestations of the same condition should not be considered CCs for one another;
- Specific and nonspecific (that is, not otherwise specified (NOS)) diagnosis codes for the same condition should not be considered CCs for one another;
- Codes for the same condition that cannot coexist, such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant, should not be considered CCs for one another;
- Codes for the same condition in anatomically proximal sites should not be considered CCs for one another; and
- Closely related conditions should not be considered CCs for one another.

The creation of the CC Exclusions List was a major project involving hundreds of codes. We have continued to review the remaining CCs to identify additional exclusions and to remove diagnoses from the master list that have been shown not to meet the definition of a CC. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50541) for detailed information regarding revisions that were made to the CC Exclusion Lists under the ICD–9–CM MS–DRGs.

For FY 2017, we are proposing changes to the ICD–10 MS–DRGs Version 34 CC Exclusion List. Therefore, we have developed Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2017; Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2017; Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2017; and Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2017. Each of these principal diagnosis codes for which there is a CC exclusion is shown in Table 6G.2. with an asterisk and the conditions that will not count as a CC are provided in an indented column immediately following the affected principal diagnosis. Beginning with discharges on or after October 1 of each year, the indented diagnoses are not recognized by the GROUPER as valid CCs for the asterisked principal diagnoses. Tables 6G and 6H associated with this proposed rule are available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

To capture new and deleted diagnosis and procedure codes, for FY 2017, we have developed Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, and Table 6C—Invalid Diagnosis Codes to this proposed rule. However, they are not published in the Addendum to this proposed rule but are available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*, as described in section VI. of the Addendum to this proposed rule. We note that while we did not specifically develop a Table 6E.—Revised Diagnosis Code Titles for this proposed rule, a document containing the FY 2017 revised diagnosis code titles, as well as new diagnosis codes that have been finalized to date since implementation of the partial code freeze, was made available in advance in response to requests from the health care industry. During the March 9–10, 2016 ICD–10 Coordination and Maintenance Committee meeting, a discussion regarding this document was presented. Participants were informed that the document titled "FY 2017 New Released ICD–10–CM Codes" would contain the information that would otherwise be included for this table. This document has been posted along with the other March 9–10, 2016 ICD–10 Coordination and Maintenance Committee meeting materials on the CDC Web site at: *http://www.cdc.gov/nchs/icd/icd9cm_maintenance.htm.*

In addition, we did not specifically develop a Table 6F.—Revised Procedure Code Titles for this proposed rule. However, a document containing the FY 2017 revised procedure code titles, as well as new procedure codes that have been finalized to date since implementation of the partial code freeze, was made available in advance in response in response to requests from the health care industry. During the March 9–10, 2016 ICD–10 Coordination and Maintenance Committee meeting, a discussion regarding this document was presented. Participants were informed that the document titled "FY 2017 New Revised ICD–10–PCS Codes" would contain the information that would otherwise be included for this table. This document is posted on the CMS Web site at: *https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials-Items/2016-03-09-MeetingMaterials.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending.*

As mentioned in section II.F.14. of this proposed rule, we are proposing additions and deletions to the MS–DRG MCC and CC Lists for FY 2017 based on the creation of new ICD–10–CM codes. This information is available in Tables 6I.1 (Proposed Additions to the MCC List—FY 2017), 6I.2 (Proposed Deletions to the MCC List—FY 2017), 6J.1 (Proposed Additions to the CC List—FY 2017), and 6J.2 (Proposed Deletions to the CC List—FY 2017). However, they are not published in the Addendum to this proposed rule but are available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*, as described in section VI. of the Addendum to this proposed rule.

16. Review of Procedure Codes in MS DRGs 981 Through 983; 984 Through 986; and 987 Through 989

Each year, we review cases assigned to MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively); MS–DRGs 984, 985, and 986 (Prostatic O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively); and MS–DRGs 987, 988, and 989 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to determine whether it would be appropriate to change the procedures assigned among these MS–DRGs. MS–DRGs 981 through 983, 984 through 986, and 987 through 989 are reserved for those cases in which none of the O.R. procedures performed are related to the principal diagnosis. These MS–DRGs are intended to capture atypical cases, that is, those cases not occurring with sufficient frequency to represent a distinct, recognizable clinical group. Under ICD–9–CM, MS–DRGs 984 through 986 are assigned to those discharges in which one or more of the following prostatic procedures are performed and are unrelated to the principal diagnosis:

- 60.0 (Incision of prostate);
- 60.12 (Open biopsy of prostate);
- 60.15 (Biopsy of periprostatic tissue);
- 60.18 (Other diagnostic procedures on prostate and periprostatic tissue);
- 60.21 (Transurethral prostatectomy);
- 60.29 (Other transurethral prostatectomy);
- 60.61 (Local excision of lesion of prostate);
- 60.69 (Prostatectomy, not elsewhere classified);
- 60.81 (Incision of periprostatic tissue);
- 60.82 (Excision of periprostatic tissue);
- 60.93 (Repair of prostate);
- 60.94 (Control of (postoperative) hemorrhage of prostate);
- 60.95 (Transurethral balloon dilation of the prostatic urethra);
- 60.96 (Transurethral destruction of prostate tissue by microwave thermotherapy);
- 60.97 (Other transurethral destruction of prostate tissue by other thermotherapy); and
- 60.99 (Other operations on prostate).

Under the ICD–10 MS–DRGs Version 33, the comparable ICD–10–PCS code translations for the above list of codes are available in Table 6P.2. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*). All remaining O.R. procedures are assigned to MS–DRGs 981 through 983 and 987 through 989, with MS–DRGs 987 through 989 assigned to those discharges in which the only procedures performed are nonextensive procedures that are unrelated to the principal diagnosis.

We refer the reader to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50544 through 50545) for detailed information regarding modifications that were made to the former ICD–9–CM CMS DRG 468 (MS–DRGs 981 through 983), CMS DRG 476 (MS–DRGs 984 through 986), and CMS DRG 477 (MS–DRGs 987 through 989) with regard to the movement of procedure codes. We note that no procedure codes were moved from these DRGs from FY 2008 through FY 2016.

Our review of MedPAR claims data showed that there are no cases that merited movement or should logically be reassigned from ICD–10 MS–DRGs 984 through 986 to any of the other MDCs. Therefore, for FY 2017, we are not proposing to change the procedures assigned among these MS–DRGs. We are inviting public comments on our proposal to maintain the current structure of these MS–DRGs.

a. Moving Procedure Codes From MS–DRGs 981 Through 983 or MS–DRGs 987 Through 989 Into MDCs

We annually conduct a review of procedures producing assignment to MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 987 through 989 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) on the basis of volume, by procedure, to see if it would be appropriate to move procedure codes out of these MS–DRGs into one of the surgical MS–DRGs for the MDC into which the principal diagnosis falls. The data are arrayed in two ways for comparison purposes. We look at a frequency count of each major operative procedure code. We also compare procedures across MDCs by volume of procedure codes within each MDC.

We identify those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical MS–DRGs for the MDC in which the diagnosis falls. Upon review of the claims data from the December 2015 update of the FY 2015 MedPAR file, we did not find any cases that merited movement or that should logically be assigned to any of the other MDCs. Therefore, for FY 2017, we are not proposing to remove any procedures from MS–DRGs 981 through 983 or MS–DRGs 987 through 989 into one of the surgical MS–DRGs for the MDC into which the principal diagnosis is assigned. We are inviting public comments on our proposal to maintain the current structure of these MS–DRGs.

b. Reassignment of Procedures Among MS–DRGs 981 Through 983, 984 Through 986, and 987 Through 989

We also reviewed the list of ICD–10–PCS procedures that, when in combination with their principal diagnosis code, result in assignment to MS–DRGs 981 through 983, 984 through 986, or 987 through 989, to ascertain whether any of those procedures should be reassigned from one of those three groups of MS–DRGs to another of the three groups of MS–DRGs based on average costs and the length of stay. We look at the data for trends such as shifts in treatment practice or reporting practice that would make the resulting MS–DRG assignment illogical. If we find these shifts, we would propose to move cases to keep the MS–DRGs clinically similar or to provide payment for the cases in a similar manner. Generally, we move only those procedures for which we have an adequate number of discharges to analyze the data.

There are no cases representing shifts in treatment practice or reporting practice that would make the resulting MS–DRG assignment illogical, or that merited movement so that cases should logically be assigned to any of the other MDCs. Therefore, for FY 2017, we are not proposing to move any procedure codes among these MS–DRGs. We are inviting public comments on our proposal.

c. Adding Diagnosis or Procedure Codes to MDCs

Based on the review of cases in the MDCs, we are proposing to add multiple diagnosis and procedure codes to MDCs for FY 2017 to address replication issues. We discuss each of these proposals below.

(1) Angioplasty of Extracranial Vessel

In the ICD–9–CM MS–DRGs Version 32, procedures describing angioplasty of an extracranial vessel were assigned to MDC 1 (Diseases and Disorders of the Nervous System) under MS–DRGs 037, 038, and 039 (Extracranial Procedures with MCC, with CC, or without CC/MCC, respectively). Under ICD–9–CM, more than one ICD–9–CM code could be reported for these procedures, depending on the approach that was documented. For example, ICD–9–CM procedure code 00.61 (Percutaneous angioplasty of extracranial vessel(s)) would have been appropriately reported if the percutaneous approach was documented, and procedure code 39.50 (Angioplasty of other non-coronary vessel(s)) would have been appropriately reported if a specified approach was not documented.

A replication issue for 41 ICD–10–PCS procedure codes describing angioplasty with the open approach was identified after implementation of the ICD–10 MS–DRGs Version 33. In the code translation, these 41 ICD–10–PCS procedure codes were grouped and assigned to ICD–10 MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with

MCC, with CC, and without CC/MCC, respectively). However, these procedure codes should have been grouped to ICD–10 MS–DRGs 037 through 039 when a principal diagnosis was reported under MDC 1.

To resolve this replication issue, we are proposing to add the 41 ICD–10–PCS procedure codes listed in the following table to ICD–10 MS–DRGs 037 through 039 under MDC 1.

ICD–10–PCS procedure code	Description
037H04Z	Dilation of right common carotid artery with drug-eluting intraluminal device, open approach.
037H0DZ	Dilation of right common carotid artery with intraluminal device, open approach.
037H0ZZ	Dilation of right common carotid artery, open approach.
037J04Z	Dilation of left common carotid artery with drug-eluting intraluminal device, open approach.
037J0DZ	Dilation of left common carotid artery with intraluminal device, open approach.
037J0ZZ	Dilation of left common carotid artery, open approach.
037K04Z	Dilation of right internal carotid artery with drug-eluting intraluminal device, open approach.
037K0DZ	Dilation of right internal carotid artery with intraluminal device, open approach.
037K0ZZ	Dilation of right internal carotid artery, open approach.
037L04Z	Dilation of left internal carotid artery with drug-eluting intraluminal device, open approach.
037L0DZ	Dilation of left internal carotid artery with intraluminal device, open approach.
037L0ZZ	Dilation of left internal carotid artery, open approach.
037M04Z	Dilation of right external carotid artery with drug-eluting intraluminal device, open approach.
037M0DZ	Dilation of right external carotid artery with intraluminal device, open approach.
037M0ZZ	Dilation of right external carotid artery, open approach.
037N04Z	Dilation of left external carotid artery with drug-eluting intraluminal device, open approach.
037N0DZ	Dilation of left external carotid artery with intraluminal device, open approach.
037N0ZZ	Dilation of left external carotid artery, open approach.
037P04Z	Dilation of right vertebral artery with drug-eluting intraluminal device, open approach.
037P0DZ	Dilation of right vertebral artery with intraluminal device, open approach.
037P0ZZ	Dilation of right vertebral artery, open approach.
037Q04Z	Dilation of left vertebral artery with drug-eluting intraluminal device, open approach.
037Q0DZ	Dilation of left vertebral artery with intraluminal device, open approach.
037Q0ZZ	Dilation of left vertebral artery, open approach.
037Y04Z	Dilation of upper artery with drug-eluting intraluminal device, open approach.
037Y0DZ	Dilation of upper artery with intraluminal device, open approach.
037Y0ZZ	Dilation of upper artery, open approach.
057M0DZ	Dilation of right internal jugular vein with intraluminal device, open approach.
057M0ZZ	Dilation of right internal jugular vein, open approach.
057N0DZ	Dilation of left internal jugular vein with intraluminal device, open approach.
057N0ZZ	Dilation of left internal jugular vein, open approach.
057P0DZ	Dilation of right external jugular vein with intraluminal device, open approach.
057P0ZZ	Dilation of right external jugular vein, open approach
057Q0DZ	Dilation of left external jugular vein with intraluminal device, open approach.
057Q0ZZ	Dilation of left external jugular vein, open approach.
057R0DZ	Dilation of right vertebral vein with intraluminal device, open approach.
057R0ZZ	Dilation of right vertebral vein, open approach.
057S0DZ	Dilation of left vertebral vein with intraluminal device, open approach.
057S0ZZ	Dilation of left vertebral vein, open approach.
057T0DZ	Dilation of right face vein with intraluminal device, open approach.
057T0ZZ	Dilation of right face vein, open approach.

We are inviting public comments on our proposal to add the above listed codes to ICD–10 MS–DRGs 037, 038, and 039 (Extracranial Procedures with MCC, with CC, or without CC/MCC, respectively) under MDC 1, effective October 1, 2016, for the ICD–10 MS–DRGs Version 34.

(2) Excision of Abdominal Arteries

In the ICD–9–CM MS–DRGs Version 32, procedures involving excision of a vessel and anastomosis, such as those performed for the treatment of an abdominal artery aneurysm (aneurysmectomy), are identified with procedure code 38.36 (Resection of vessel with anastomosis, abdominal arteries) and are assigned to the following MDCs and MS–DRGs:

- MDC 5 (Diseases and Disorders of the Circulatory System): MS–DRGs 270 through 272 (Other Major Cardiovascular Procedures with MCC, with CC and without CC/MCC, respectively);
- MDC 6 (Diseases and Disorders of the Digestive System): MS–DRGs 356 through 358 (Other Digestive System O.R. Procedures with MCC, with CC and without CC/MCC, respectively);
- MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract): MS–DRGs 673 through 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC and without CC/MCC, respectively);
- MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs): MS–DRGs 907 through 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively); and
- MDC 24 (Multiple Significant Trauma): MS–DRG 957 through 959 (Other O.R. Procedures for Multiple Significant Trauma without CC/MCC).

A replication issue for 34 ICD–10–PCS procedure codes describing aneurysmectomy procedures with the open and percutaneous endoscopic approach was identified after implementation of the ICD–10 MS–DRGs Version 33. For example, cases with a principal diagnosis of I72.2 (Aneurysm of renal artery) and procedure code 04BA0ZZ (Excision of left renal artery, open approach) are resulting in assignment to ICD–10 MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) instead of to MDC 11 in MS–DRGs 673 through 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC, and without CC/MCC, respectively).

To resolve this replication issue, we are proposing to add the 34 ICD–10–PCS procedure codes listed in the following table that are comparable translations of ICD–9–CM procedure code 38.36 to ICD–10 MDCs 6, 11, 21, and 24. We note that there is no replication issue related to MDC 5 as the ICD–10–PCS procedure codes listed in the table below group there appropriately.

ICD–10–PCS procedure code	Description
04B10ZZ	Excision of celiac artery, open approach.
04B14ZZ	Excision of celiac artery, percutaneous endoscopic approach.
04B20ZZ	Excision of gastric artery, open approach.
04B24ZZ	Excision of gastric artery, percutaneous endoscopic approach.
04B30ZZ	Excision of hepatic artery, open approach.
04B34ZZ	Excision of hepatic artery, percutaneous endoscopic approach.
04B40ZZ	Excision of splenic artery, open approach.
04B44ZZ	Excision of splenic artery, percutaneous endoscopic approach.
04B50ZZ	Excision of superior mesenteric artery, open approach.
04B54ZZ	Excision of superior mesenteric artery, percutaneous endoscopic approach.
04B60ZZ	Excision of right colic artery, open approach.
04B64ZZ	Excision of right colic artery, percutaneous endoscopic approach.
04B70ZZ	Excision of left colic artery, open approach.
04B74ZZ	Excision of left colic artery, percutaneous endoscopic approach.
04B80ZZ	Excision of middle colic artery, open approach.
04B84ZZ	Excision of middle colic artery, percutaneous endoscopic approach.
04B90ZZ	Excision of right renal artery, open approach.
04B94ZZ	Excision of right renal artery, percutaneous endoscopic approach.
04BA0ZZ	Excision of left renal artery, open approach.
04BA4ZZ	Excision of left renal artery, percutaneous endoscopic approach.
04BB0ZZ	Excision of inferior mesenteric artery, open approach.
04BB4ZZ	Excision of inferior mesenteric artery, percutaneous endoscopic approach.
04BC0ZZ	Excision of right common iliac artery, open approach.
04BC4ZZ	Excision of right common iliac artery, percutaneous endoscopic approach.
04BD0ZZ	Excision of left common iliac artery, open approach.
04BD4ZZ	Excision of left common iliac artery, percutaneous endoscopic approach.
04BE0ZZ	Excision of right internal iliac artery, open approach.
04BE4ZZ	Excision of right internal iliac artery, percutaneous endoscopic approach.
04BF0ZZ	Excision of left internal iliac artery, open approach.
04BF4ZZ	Excision of left internal iliac artery, percutaneous endoscopic approach.
04BH0ZZ	Excision of right external iliac artery, open approach.
04BH4ZZ	Excision of right external iliac artery, percutaneous endoscopic approach.
04BJ0ZZ	Excision of left external iliac artery, open approach.
04BJ4ZZ	Excision of left external iliac artery, percutaneous endoscopic approach.

Adding these procedures to those MDCs in the ICD–10 MS–DRGs Version 34 will result in a more accurate replication for the same procedure under the ICD–9–CM MS–DRGs Version 32. We also are proposing that these procedure codes be assigned to the corresponding MS–DRGs in each respective MDC as listed above. The proposed changes would eliminate erroneous assignment to MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) for these procedures.

We are inviting public comments on our proposal to add the above listed codes to MDCs 6, 11, 21, and 24 in the corresponding MS–DRGs, effective October 1, 2016, in the ICD–10 MS–DRGs Version 34.

(3) Excision of Retroperitoneal Tissue

In the ICD–9–CM MS–DRGs Version 32, procedures involving excision of a retroperitoneal lesion (or tissue), such as those performed for the treatment of a neoplasm, are identified with procedure code 54.4 (Excision or destruction of peritoneal tissue) and are assigned to a number of MDCs and MS–DRGs across a variety of body systems, some of which include the following:

- MDC 6 (Diseases and Disorders of the Digestive System): MS–DRGs 356 through 358 (Other Digestive System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively);
- MDC 7 (Diseases and Disorders of the Hepatobiliary System and Pancreas): MS–DRGs 423 through 425 (Other Hepatobiliary or Pancreas O.R. Procedures with MCC, with CC, and without CC/MCC, respectively); and
- MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders): MS–DRGs 628 through 630 (Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC, with CC, and without CC/MCC, respectively).

A replication issue for the ICD–10–PCS procedure codes describing excision of retroperitoneum that involves MDC 6 was identified after implementation of the ICD–10 MS–DRGs Version 33. These procedure codes are ICD–10–PCS codes 0WBH0ZZ (Excision of retroperitoneum, open approach), 0WBH3ZZ (Excision of retroperitoneum, percutaneous approach), and 0WBH4ZZ (Excision of retroperitoneum, percutaneous endoscopic approach). For example, when an ICD–10–CM diagnosis code such as D20.0 (Benign neoplasm of soft tissue of retroperitoneum) is reported with any one of these three ICD–10–PCS procedure codes, the case is assigned to MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

To resolve this replication issue, we are proposing to add the three ICD–10–PCS procedure codes to MDC 6 in MS–DRGs 356 through 358 (Other Digestive System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively). This would result in a more accurate replication of the comparable procedure under the ICD–9–CM MS–DRGs Version

32. The proposed changes also would eliminate erroneous assignment to MS–DRGs 981 through 983 for these procedures.

We are inviting public comments on our proposal to add the three ICD–10–PCS codes describing excision of retroperitoneum to MDC 6 in MS–DRGs 356 through 358, effective October 1, 2016, in the ICD–10 MS–DRGs Version 34.

(4) Occlusion of Vessels: Esophageal Varices

In the ICD–9–CM MS–DRGs Version 32, procedures including ligation or surgical occlusion of esophageal varices are identified with procedure code 42.91 (Ligation of esophageal varices) and are assigned to MDC 6 (Diseases and Disorders of the Digestive System) under MS–DRGs 326 through 328 (Stomach, Esophageal and Duodenal Procedures with MCC, with CC, and without CC/MCC, respectively) and MDC 7 (Diseases and Disorders of the Hepatobiliary System and Pancreas) under MS–DRGs 423 through 425 (Other Hepatobiliary or Pancreas O.R. procedures with MCC, with CC, and without CC/MCC, respectively).

A replication issue for MDC 7 involving ICD–10–PCS procedure codes 06L30CZ (Occlusion of esophageal vein with extraluminal device, open approach) and 06L30DZ (Occlusion of esophageal vein with intraluminal device, open approach) was identified in the ICD–10 MS–DRGs Version 33 after implementation on October 1, 2015. For instance, when an ICD–10–CM diagnosis code such as K70.30 (Alcoholic cirrhosis of liver without ascites) is reported with either one of the ICD–10–PCS procedure codes, it results in assignment to MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

To resolve this replication issue, we are proposing to add the two ICD–10–PCS procedure codes describing occlusion of esophageal vein to MDC 7 under MS–DRGs 423 through 425. This will result in a more accurate replication of the comparable procedure under the ICD–9–CM MS–DRGs Version 32. The proposed changes also would eliminate erroneous assignment to MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) for these procedures.

We are inviting public comments on our proposal to add ICD–10–PCS procedure codes 06L30CZ and 06L30DZ to MDC 7 under MS–DRGs 423 through 425, effective October 1, 2016, in the ICD–10 MS–DRGs Version 34.

(5) Excision of Vulva

In the ICD–9–CM MS–DRGs Version 32, procedures involving excision of the vulva are identified with procedure code 71.3 (Other local excision or destruction of vulva and perineum) and are assigned to the following MDCs and MS–DRGs:

- MDC 9 (Diseases & Disorders of the Skin, Subcutaneous Tissue and Breast): MS–DRGs 579 through 581 (Other Skin, Subcutaneous Tissue and Breast Procedures with MCC, with CC, and without CC/MCC, respectively); and
- MDC 13 (Diseases & Disorders of the Female Reproductive System): MS–DRG 746 (Vagina, cervix and vulva procedures with CC/MCC) and MS–DRG 747 (Vagina, Cervix and Vulva procedures without CC/MCC).

A replication issue involving ICD–10–PCS procedure code 0UBMXZZ (Excision of vulva, external approach) was identified after implementation of the ICD–10 MS–DRGs Version 33. For example, when cases with an ICD–10–CM principal diagnosis of code D07.1 (Carcinoma in situ of vulva) are reported with ICD–10–PCS procedure code 0UBMXZZ (Excision of vulva, external approach), they are resulting in assignment to MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

To resolve this replication issue, we are proposing to add ICD–10–PCS procedure code 0UBMXZZ to MDC 13 under MS–DRGs 746 and 747. Adding procedure code 0UBMXZZ to MDC 13 in MS–DRGs 746 and 747 would result in a more accurate replication of the comparable procedure under the ICD–9–CM MS–DRGs Version 32. The proposed changes also would eliminate erroneous assignment to MS–DRGs 981 through 983 for these procedures. In addition, the proposed changes would be consistent with the assignment of other clinically similar procedures, such as ICD–10–PCS procedure code 0WBNXZZ (Excision of female perineum, external approach). Finally, we note that there is no replication issue for MDC 9 regarding this procedure code.

We are inviting public comment on our proposal to add ICD–10–PCS procedure code 0UBMXZZ to MDC 13 in MS–DRGs 746 and 747, effective October 1, 2016, in the ICD–10 MS–DRGs Version 34.

(6) Lymph Node Biopsy

In the ICD–9–CM MS–DRGs Version 32, procedures involving a lymph node biopsy are identified with procedure code 40.11 (Biopsy of lymphatic structure), which may be assigned to several MDCs representing various body systems. Under the ICD–10 MS–DRGs Version 33, this procedure has 114 ICD–10–PCS procedure codes considered to be comparable translations that describe diagnostic drainage or excision of specified lymphatic structures and also warrant assignment to the same MDCs across various body systems.

A replication issue for the lymph node biopsy procedure involving MDC 4 (Diseases and Disorders of the Respiratory System) under the ICD–10 MS–DRGs Version 33 was identified after implementation on October 1, 2015. For example, when a respiratory system diagnosis is reported with the comparable ICD–10–PCS procedure code 07B74ZX (Excision of thorax lymphatic, percutaneous endoscopic approach, diagnostic), the case is assigned to MS–DRGs 987 through 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

To resolve this replication issue, we are proposing to add ICD–10–PCS procedure code 07B74ZX to MDC 4 under MS–DRGs 166 through 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) to more accurately replicate assignment of the comparable procedure code under the ICD–9–CM MS–DRGs Version 32.

While reviewing that specific example, we also identified two other comparable ICD–10–PCS procedure code translations of ICD–9–CM procedure code 40.11 (Biopsy of lymphatic structure) describing diagnostic excision of thoracic lymphatic structures that were not replicated consistent with the ICD–9–CM MS–DRGs Version 32. These are ICD–10–PCS procedure codes 07B70ZX (Excision of thorax lymphatic, open approach, diagnostic) and 07B73ZX (Excision of thorax lymphatic, percutaneous approach, diagnostic). Therefore, we are proposing to add these two ICD–10–PCS procedure codes to MDC 4 in MS–DRGs 166 through 168 as well.

Adding ICD–10–PCS procedure codes 07B74ZX, 07B70ZX, and 07B73ZX that describe diagnostic excision of thoracic lymphatic structures to MDC 4 under MS–DRGs 166 through 168 would result in a more accurate replication of the comparable procedure under ICD–9–CM MS–DRGs Version 32. The proposed changes would eliminate erroneous assignment to MS–DRGs 987 through 989 for these procedures.

We are inviting public comments on our proposal to add ICD–10–PCS procedure codes 07B74ZX, 07B70ZX, and 07B73ZX to the ICD–10 MS–DRGs Version 34 for MS–DRGs 166 through 168 in MDC 4, effective October 1, 2016.

(7) Obstetrical Laceration Repair

A replication issue for eight ICD–10–PCS procedure codes describing procedures that may be performed for the repair of obstetrical lacerations was identified after implementation of the ICD–10 MS–DRGs Version 33. These codes are:

ICD–10–PCS procedure code	Description
0DQQ0ZZ	Repair anus, open approach.
0DQQ3ZZ	Repair anus, percutaneous approach.
0DQQ4ZZ	Repair anus, percutaneous endoscopic approach.
0DQQ7ZZ	Repair anus, via natural or artificial opening.
0DQQ8ZZ	Repair anus, via natural or artificial opening endoscopic.
0DQR0ZZ	Repair anal sphincter, open approach.
0DQR3ZZ	Repair anal sphincter, percutaneous approach.
0DQR4ZZ	Repair anal sphincter, percutaneous endoscopic approach.

We discovered that the ICD–10 MDC and MS–DRG assignment are not consistent with other ICD–10–PCS procedure codes that identify and describe clinically similar procedures for the repair of obstetrical lacerations which are coded and reported based on the extent of the tear. For example, ICD–10–PCS procedure code 0DQP0ZZ (Repair rectum, open approach) is appropriately assigned to MDC 14 (Pregnancy, Childbirth and the Puerperium) under MS–DRG 774 (Vaginal Delivery with Complicating Diagnoses). This procedure may be performed in the treatment of a fourth-degree perineal laceration involving the rectal mucosa. In contrast, ICD–10–PCS procedure code 0DQR0ZZ (Repair anal sphincter, open approach), when reported for repair of a perineal laceration, currently results in assignment to MS–DRGs 987 through 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis).

To resolve this replication issue, we are proposing to add these eight ICD–10–PCS procedure codes to MDC 14 in MS–DRG 774. The proposed changes would eliminate erroneous assignment to MS–DRGs 987 through 989 for these procedures.

We are inviting public comments on our proposal to add the eight listed codes to MDC 14 under MS–DRG 774, effective October 1, 2016, in the ICD–10 MS–DRGs Version 34.

17. Proposed Changes to the ICD–10–CM and ICD–10–PCS Coding Systems

a. ICD–10 Coordination and Maintenance Committee

In September 1985, the ICD–9–CM Coordination and Maintenance Committee was formed. This is a Federal interdepartmental committee, co-chaired by the National Center for Health Statistics (NCHS), the Centers for Disease Control and Prevention, and CMS, charged with maintaining and updating the ICD–9–CM system. The final update to ICD–9–CM codes was to be made on October 1, 2013. Thereafter, the name of the Committee was changed to the ICD–10 Coordination and Maintenance Committee, effective with the March 19–20, 2014 meeting. The ICD–10 Coordination and Maintenance Committee addresses updates to the ICD–10–CM and ICD–10–PCS coding systems. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the coding systems to reflect newly developed procedures and technologies and newly identified diseases. The Committee is also responsible for promoting the use of Federal and non-Federal educational programs and other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The official list of ICD–9–CM diagnosis and procedure codes by fiscal year can be found on the CMS Web site at: *http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/codes.html.* The official list of ICD–10–CM and ICD–10–PCS codes can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/index.html.*

The NCHS has lead responsibility for the ICD–10–CM and ICD–9–CM diagnosis codes included in the Tabular List and Alphabetic Index for Diseases, while CMS has lead responsibility for the ICD–10–PCS and ICD–9–CM procedure codes included in the Tabular List and Alphabetic Index for Procedures.

The Committee encourages participation in the previously mentioned process by health-related organizations. In this regard, the Committee holds public meetings for discussion of educational issues and proposed coding changes. These meetings provide an opportunity for representatives of recognized organizations in the coding field, such as the American Health Information Management Association (AHIMA), the American Hospital Association (AHA), and various physician specialty groups, as well as individual physicians, health information management professionals, and other members of the public, to contribute ideas on coding matters. After considering the opinions expressed at the public meetings and in writing, the Committee formulates recommendations, which then must be approved by the agencies.

The Committee presented proposals for coding changes for implementation in FY 2017 at a public meeting held on September 22–23, 2015, and finalized the coding changes after consideration of comments received at the meetings and in writing by November 13, 2015.

The Committee held its 2016 meeting on March 9–10, 2016. It was announced at this meeting that any new ICD–10–CM/PCS codes for which there was consensus of public support and for which complete tabular and indexing changes would be made by May 2016 would be included in the October 1, 2016 update to ICD–10–CM/ICD–10–PCS. As discussed in earlier sections of this preamble, there are new and deleted ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes that are captured in Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, and Table 6C.—Invalid Diagnosis Codes for the proposed rule, which are available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* Because of the length of these tables, they are not published in the Addendum to this proposed rule. Rather, they are available via the Internet as discussed in section VI. of the Addendum to this proposed rule.

Live Webcast recordings of the discussions of procedure codes at the Committee's September 22–23, 2015 meeting and March 9–10, 2016 meeting can be obtained from the CMS Web site at: *http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/icD9ProviderDiagnosticCodes/03_meetings.asp.* The minutes of the discussions of diagnosis codes at the September 23–24, 2015 meeting and March 9–10, 2016 meeting are found at: *http://www.cdc.gov/nchs/icd/icd9cm_maintenance.html.* These Web sites also provide detailed information about the Committee, including information on requesting a new code, attending a Committee meeting, and timeline requirements and meeting dates.

We encourage commenters to address suggestions on coding issues involving diagnosis codes to: Donna Pickett, Co-Chairperson, ICD–10 Coordination and Maintenance Committee, NCHS, Room 2402, 3311 Toledo Road, Hyattsville, MD 20782. Comments may be sent by Email to: *nchc@cdc.gov.*

Questions and comments concerning the procedure codes should be addressed to: Patricia Brooks, Co-Chairperson, ICD–10 Coordination and Maintenance Committee, CMS, Center for Medicare Management, Hospital and Ambulatory Policy Group, Division of Acute Care, C4–08–06, 7500 Security Boulevard, Baltimore, MD 21244–1850. Comments may be sent by Email to: *ICDProcedureCodeRequest@cms.hhs.gov.*

In the September 7, 2001 final rule implementing the IPPS new technology add-on payments (66 FR 46906), we indicated we would attempt to include proposals for procedure codes that would describe new technology discussed and approved at the Spring meeting as part of the code revisions effective the following October.

Section 503(a) of Public Law 108–173 included a requirement for updating diagnosis and procedure codes twice a year instead of a single update on October 1 of each year. This requirement was included as part of the amendments to the Act relating to recognition of new technology under the IPPS. Section 503(a) amended section 1886(d)(5)(K) of the Act by adding a clause (vii) which states that the Secretary shall provide for the addition of new diagnosis and procedure codes on April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) until the fiscal year that begins after such date. This requirement improves the recognition of new technologies under the IPPS system by providing information on these new technologies at an earlier date. Data will be available 6 months earlier than would be possible with updates occurring only once a year on October 1.

While section 1886(d)(5)(K)(vii) of the Act states that the addition of new diagnosis and procedure codes on April 1 of each year shall not require the Secretary to adjust the payment, or DRG classification, under section 1886(d) of the Act until the fiscal year that begins after such date, we have to update the DRG software and other systems in order to recognize and accept the new codes. We also publicize the code changes and the need for a mid-year systems update by providers to identify the new codes. Hospitals also have to obtain the new code books and encoder updates, and make other system changes in order to identify and report the new codes.

The ICD–10 (previously the ICD–9–CM) Coordination and Maintenance Committee holds its meetings in the spring and fall in order to update the codes and the applicable payment and reporting systems by October 1 of each year. Items are placed on the agenda for the Committee meeting if the request is received at least 2 months prior to the meeting. This requirement allows time for staff to review and research the coding issues and prepare material for discussion at the meeting. It also allows time for the topic to be publicized in meeting announcements in the **Federal Register** as well as on the CMS Web site. Final decisions on code title revisions are currently made by March 1 so that these titles can be included in the IPPS proposed rule. A complete addendum describing details of all diagnosis and procedure coding changes, both tabular and index, is published on the CMS and NCHS Web sites in May of each year. Publishers of coding books and software use this information to modify their products that are used by health care providers. This 5-month time period has proved to be necessary for hospitals and other providers to update their systems.

A discussion of this timeline and the need for changes are included in the December 4–5, 2005 ICD–9–CM Coordination and Maintenance Committee Meeting minutes. The public agreed that there was a need to hold the fall meetings earlier, in September or October, in order to meet the new implementation dates. The public provided comment that additional time would be needed to update hospital systems and obtain new code books and coding software. There was considerable concern expressed about the impact this new April update would have on providers.

In the FY 2005 IPPS final rule, we implemented section 1886(d)(5)(K)(vii) of the Act, as added by section 503(a) of Public Law 108–173, by developing a mechanism for approving, in time for the April update, diagnosis and procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. We also established the following process for making these determinations. Topics considered during the Fall ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee meeting are considered for an April 1 update if a strong and convincing case is made by the requester at the Committee's public meeting. The request must identify the reason why a new code is needed in April for purposes of the new technology process. The participants at the meeting and those reviewing the Committee meeting summary report are provided the opportunity to comment on this expedited request. All other topics are considered for the October 1 update. Participants at the Committee meeting are encouraged to comment on all such requests. There were no requests approved for an expedited April 1, 2016 implementation of a code at the September 22–23, 2015 Committee meeting. Therefore, there were no new codes implemented on April 1, 2016.

ICD–9–CM addendum and code title information is published on the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/icD9ProviderDiagnosticCodes/01overview.asp#TopofPage.* ICD–10–CM and ICD–10–PCS addendum and code title information is published on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/index.html.* Information on ICD–10–CM diagnosis codes, along with the Official ICD–10–CM Coding Guidelines, can also be found on the CDC Web site at: *http://www.cdc.gov/nchs/icd/icd10.htm.* Information on new, revised, and deleted ICD–10–CM/ICD–10–PCS codes is also provided to the AHA for publication in the *Coding Clinic for ICD–10.* AHA also distributes information to publishers and software vendors.

CMS also sends copies of all ICD–10–CM and ICD–10–PCS coding changes to its Medicare contractors for use in updating their systems and providing education to providers.

The code titles are adopted as part of the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee process. Therefore, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules.

b. Code Freeze

In the January 16, 2009 ICD–10–CM and ICD–10–PCS final rule (74 FR 3340), there was a discussion of the need for a partial or total freeze in the annual updates to both ICD–9–CM and ICD–10–CM and ICD–10–PCS codes. The public comment addressed in that final rule stated that the annual code set updates should cease 1 year prior to the implementation of ICD–10. The commenters stated that this freeze of code updates would allow for instructional and/or coding software programs to be designed and purchased early, without concern that an upgrade would take place immediately before the compliance date, necessitating additional updates and purchases.

HHS responded to comments in the ICD–10 final rule that the ICD–9–CM Coordination and Maintenance Committee has jurisdiction over any action impacting the ICD–9–CM and ICD–10 code sets. Therefore, HHS indicated that the issue of consideration of a moratorium on updates to the ICD–9–CM, ICD–10–CM, and ICD–10–PCS code sets in anticipation of the adoption of ICD–10–CM and ICD–10–PCS would be addressed through the Committee at a future public meeting.

The code freeze was discussed at multiple meetings of the ICD–9–CM Coordination and Maintenance Committee and public comment was actively solicited. The Committee evaluated all comments from participants attending the Committee meetings as well as written comments that were received. The Committee also considered the delay in implementation of ICD–10 until October 1, 2014. There was an announcement at the September 19, 2012 ICD–9–CM Coordination and Maintenance Committee meeting that a partial freeze of both ICD–9–CM and ICD–10 codes will be implemented as follows:

- The last regular annual update to both ICD–9–CM and ICD–10 code sets was made on October 1, 2011.
- On October 1, 2012 and October 1, 2013, there will be only limited code updates to both ICD–9–CM and ICD–10 code sets to capture new technology and new diseases.
- On October 1, 2014, there were to be only limited code updates to ICD–10 code sets to capture new technology and diagnoses as required by section 503(a) of Public Law 108–173. There were to be no updates to ICD–9–CM on October 1, 2014.
- On October 1, 2015, one year after the originally scheduled implementation of ICD–10, regular updates to ICD–10 were to begin.

On May 15, 2014, CMS posted an updated Partial Code Freeze schedule on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10/ICD-9-CM-Coordination-and-Maintenance-Committee-Meetings.html.* This updated schedule provided information on the extension of the partial code freeze until 1 year after the implementation of ICD–10. As stated earlier, on April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted, which specified that the Secretary may not adopt ICD–10 prior to October 1, 2015. On August 4, 2014, the Department published a final rule with a compliance date to require the use of ICD–10 beginning October 1, 2015. The final rule also required HIPAA-covered entities to continue to use ICD–9–CM through September 30, 2015. Accordingly, the updated schedule for the partial code freeze was as follows:

- The last regular annual updates to both ICD–9–CM and ICD–10 code sets were made on October 1, 2011.
- On October 1, 2012, October 1, 2013, and October 1, 2014, there will be only limited code updates to both the ICD–9–CM and ICD–10 code sets to capture new technologies and diseases as required by section 1886(d)(5)(K) of the Act.
- On October 1, 2015, there will be only limited code updates to ICD–10 code sets to capture new technologies and diagnoses as required by section 1886(d)(5)(K) of the Act. There will be no updates to ICD–9–CM, as it will no longer be used for reporting.
- On October 1, 2016 (1 year after implementation of ICD–10), regular updates to ICD–10 will begin.

The ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee announced that it would continue to meet twice a year during the freeze. At these meetings, the public was encouraged to comment on whether or not requests for new diagnosis and procedure codes should be created based on the need to capture new technology and new diseases. Any code requests that do not meet the criteria will be evaluated for implementation within ICD–10 one year after the implementation of ICD–10, once the partial freeze is ended.

Complete information on the partial code freeze and discussions of the issues at the Committee meetings can be found on the ICD–10 Coordination and Maintenance Committee Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/meetings.html.* A summary of the September 19, 2012 Committee meeting, along with both written and audio transcripts of this meeting, is posted on the Web site at: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-and-M-Meeting-Materials-Items/2012-09-19-MeetingMaterials.html.*

This partial code freeze dramatically decreased the number of codes created each year as shown by the following information.

TOTAL NUMBER OF CODES AND CHANGES IN TOTAL NUMBER OF CODES PER FISCAL YEAR

ICD–9–CM Codes			ICD–10–CM and ICD–10–PCS Codes		
Fiscal year	Number	Change	Fiscal year	Number	Change
FY 2009 (October 1, 2008)			FY 2009		
Diagnoses	14,025	348	ICD–10–CM	68,069	+5
Procedures	3,824	56	ICD–10–PCS	72,589	−14,327
FY 2010 (October 1, 2009)			FY 2010		
Diagnoses	14,315	290	ICD–10–CM	69,099	+1,030
Procedures	3,838	14	ICD–10–PCS	71,957	−632
FY 2011 (October 1, 2010)					
Diagnoses	14,432	117	ICD–10–CM	69,368	+269
Procedures	3,859	21	ICD–10–PCS	72,081	+124
FY 2012 (October 1, 2011)			FY 2012		
Diagnoses	14,567	135	ICD–10–CM	69,833	+465

TOTAL NUMBER OF CODES AND CHANGES IN TOTAL NUMBER OF CODES PER FISCAL YEAR—Continued

ICD–9–CM Codes			ICD–10–CM and ICD–10–PCS Codes		
Fiscal year	Number	Change	Fiscal year	Number	Change
Procedures	3,877	18	ICD–10–PCS	71,918	−163
FY 2013 (October 1, 2012)			FY 2013		
Diagnoses	14,567	0	ICD–10–CM	69,832	−1
Procedures	3,878	1	ICD–10–PCS	71,920	+2
FY 2014 (October 1, 2013)			FY 2014		
Diagnoses	14,567	0	ICD–10–CM	69,823	−9
Procedures	3,882	4	ICD–10–PCS	71,924	+4
FY 2015 (October 1, 2014)			FY 2015		
Diagnoses	14,567	0	ICD–10–CM	69,823	0
Procedures	3,882	0	ICD–10–PCS	71,924	0
FY 2016 (October 1, 2015)			FY 2016		
Diagnoses	14,567	0	ICD–10–CM	69,823	0
Procedures	3,882	0	ICD–10–PCS	71,924	0
Proposed FY 2017 (October 1, 2016)			Proposed FY 2017		
Diagnoses	14,567	0	ICD–10–CM	71,558	0
Procedures	3,882	0	ICD–10–PCS	75,625	0

As mentioned previously, the public is provided the opportunity to comment on any requests for new diagnosis or procedure codes discussed at the ICD–10 Coordination and Maintenance Committee meeting. The public has supported only a limited number of new codes during the partial code freeze, as can be seen by previously shown data. We have gone from creating several hundred new codes each year to creating only a limited number of new ICD–9–CM and ICD–10 codes.

At the September 22–23, 2015 and March 9–10, 2016 Committee meetings, we discussed any requests we had received for new ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes that were to be implemented on October 1, 2016. We did not discuss ICD–9–CM codes. Because the partial code freeze will end on October 1, 2016, the public no longer had to comment on whether or not new ICD–10–CM and ICD–10–PCS codes should be created based on the partial code freeze criteria. We invited public comments on any code requests discussed at the September 22–23, 2015 and March 9–10, 2016 Committee meetings for implementation as part of the October 1, 2016 update. The deadline for commenting on code proposals discussed at the September 22–23, 2015 Committee meeting was November 13, 2015. The deadline for commenting on code proposals discussed at the March 9–10, 2016 Committee meeting was April 8, 2016.

18. Replaced Devices Offered Without Cost or With a Credit

a. Background

In the FY 2008 IPPS final rule with comment period (72 FR 47246 through 47251), we discussed the topic of Medicare payment for devices that are replaced without cost or where credit for a replaced device is furnished to the hospital. We implemented a policy to reduce a hospital's IPPS payment for certain MS–DRGs where the implantation of a device that has been recalled determined the base MS–DRG assignment. At that time, we specified that we will reduce a hospital's IPPS payment for those MS–DRGs where the hospital received a credit for a replaced device equal to 50 percent or more of the cost of the device.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51556 through 51557), we clarified this policy to state that the policy applies if the hospital received a credit equal to 50 percent or more of the cost of the replacement device and issued instructions to hospitals accordingly.

b. Proposed Changes for FY 2017

For FY 2017 we are proposing not to add any MS–DRGs to the policy for replaced devices offered without cost or with a credit. We are proposing to continue to include the existing MS–DRGs currently subject to the policy as displayed in the table below.

MDC	MS–DRG	MS–DRG Title
Pre-MDC	001	Heart Transplant or Implant of Heart Assist System with MCC.
Pre-MDC	002	Heart Transplant or Implant of Heart Assist System without MCC.
1	023	Craniotomy with Major Device Implant/Acute Complex CNS Principal Diagnosis with MCC or Chemo Implant.
1	024	Craniotomy with Major Device Implant/Acute Complex CNS Principal Diagnosis without MCC.
1	025	Craniotomy & Endovascular Intracranial Procedures with MCC.
1	026	Craniotomy & Endovascular Intracranial Procedures with CC.
1	027	Craniotomy & Endovascular Intracranial Procedures without CC/MCC.
1	040	Peripheral/Cranial Nerve & Other Nervous System Procedure with MCC.
1	041	Peripheral/Cranial Nerve & Other Nervous System Procedure with CC or Peripheral Neurostimulator.
1	042	Peripheral/Cranial Nerve & Other Nervous System Procedure without CC/MCC.
3	129	Major Head & Neck Procedures with CC/MCC or Major Device.
3	130	Major Head & Neck Procedures without CC/MCC.
5	215	Other Heart Assist System Implant.
5	216	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheter with MCC.
5	217	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheter with CC.
5	218	Cardiac Valve & Other Major Cardiothoracic Procedure with Cardiac Catheter without CC/MCC.
5	219	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheter with MCC.
5	220	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheter with CC.

MDC	MS–DRG	MS–DRG Title
5	221	Cardiac Valve & Other Major Cardiothoracic Procedure without Cardiac Catheter without CC/MCC.
5	222	Cardiac Defibrillator Implant with Cardiac Catheter with AMI/Heart Failure/Shock with MCC.
5	223	Cardiac Defibrillator Implant with Cardiac Catheter with AMI/Heart Failure/Shock without MCC.
5	224	Cardiac Defibrillator Implant with Cardiac Catheter without AMI/Heart Failure/Shock with MCC.
5	225	Cardiac Defibrillator Implant with Cardiac Catheter without AMI/Heart Failure/Shock without MCC.
5	226	Cardiac Defibrillator Implant without Cardiac Catheter with MCC.
5	227	Cardiac Defibrillator Implant without Cardiac Catheter without MCC.
5	242	Permanent Cardiac Pacemaker Implant with MCC.
5	243	Permanent Cardiac Pacemaker Implant with CC.
5	244	Permanent Cardiac Pacemaker Implant without CC/MCC.
5	245	AICD Generator Procedures.
5	258	Cardiac Pacemaker Device Replacement with MCC.
5	259	Cardiac Pacemaker Device Replacement without MCC.
5	260	Cardiac Pacemaker Revision Except Device Replacement with MCC.
5	261	Cardiac Pacemaker Revision Except Device Replacement with CC.
5	262	Cardiac Pacemaker Revision Except Device Replacement without CC/MCC.
5	266	Endovascular Cardiac Valve Replacement with MCC.
5	267	Endovascular Cardiac Valve Replacement without MCC.
5	268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC.
5	269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC.
5	270	Other Major Cardiovascular Procedures with MCC.
5	271	Other Major Cardiovascular Procedures with CC.
5	272	Other Major Cardiovascular Procedures without CC/MCC.
8	461	Bilateral or Multiple Major Joint Procedures Of Lower Extremity with MCC.
8	462	Bilateral or Multiple Major Joint Procedures of Lower Extremity without MCC.
8	466	Revision of Hip or Knee Replacement with MCC.
8	467	Revision of Hip or Knee Replacement with CC.
8	468	Revision of Hip or Knee Replacement without CC/MCC.
8	469	Major Joint Replacement or Reattachment of Lower Extremity with MCC.
8	470	Major Joint Replacement or Reattachment of Lower Extremity without MCC.

We are soliciting public comments on our proposal to continue to include the existing MS–DRGs currently subject to the policy and to not add any additional MS–DRGs to the policy. The final list of MS–DRGs subject to the policy for FY 2017 will be listed in the FY 2017 IPPS/LTCH PPS final rule, as well as issued to providers in the form of a Change Request (CR).

19. Other Proposed Policy Changes

a. MS–DRG GROUPER Logic

(1) Operations on Products of Conception

In the ICD–9–CM MS–DRGs Version 32, intrauterine operations that may be performed in an attempt to correct a fetal abnormality are identified by ICD–9–CM procedure code 75.36 (Correction of fetal defect). This procedure code is designated as an O.R. procedure and is assigned to MDC 14 (Pregnancy, Childbirth and the Puerperium) in MS–DRG 768 (Vaginal Delivery with O.R. Procedure Except Sterilization and/or Dilation and Curettage).

A replication issue for 208 ICD–10–PCS comparable code translations that describe operations on the products of conception (fetus) to correct fetal defects was identified during an internal review. These 208 procedure codes were inadvertently omitted from the MDC 14 GROUPER logic for ICD–10 MS–DRG 768. To resolve this replication issue, we are proposing to add the 208 ICD–10–PCS procedure codes shown in Table 6P.3a. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*) to MDC 14 in MS–DRG 768, effective October 1, 2016, in ICD–10 MS–DRGs Version 34. We are inviting public comments on our proposal.

Separate from the replication issue described above, during our internal review, we also concluded that the proposed MS–DRG logic for these intrauterine procedures under ICD–10 may not accurately represent a subset of the 208 ICD–10–PCS procedure codes (listed in Table 6P.3a.). For example, the GROUPER logic for MS–DRG 768 requires that a vaginal delivery occur during the same episode of care in which an intrauterine procedure is performed. However, this scenario may not be clinically consistent with all pregnant patients who undergo fetal surgery. For example, a pregnant patient whose fetus is diagnosed with a congenital diaphragmatic hernia (CDH) may undergo a fetoscopic endoluminal tracheal occlusion (FETO) procedure in which the pregnant patient does not subsequently deliver during the same hospital stay. The goal of this specific fetal surgery is to allow the fetus to remain in utero until its lungs have developed to increase the chance of survival. Therefore, this scenario of a patient who has fetal surgery but does not have a delivery during the same hospital stay is not appropriately captured in the GROUPER logic. We believe that further analysis is warranted regarding a future proposal for a new MS–DRG to better recognize this subset of patients.

In past rulemaking (72 FR 24700 and 24705), we have acknowledged that CMS does not have the expertise or data to maintain the DRGs in clinical areas that have very low volume in the Medicare population, including for conditions associated with and/or occurring in the maternal-fetal patient population. Additional information is needed to fully and accurately evaluate all the possible fetal conditions that may fall under similar scenarios to the one described above before making a specific proposal. Therefore, we are soliciting public comments on two clinical concepts for consideration for a possible future proposal for the FY 2018 ICD–10 MS–DRGs Version 35: (1) The ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes that describe fetal abnormalities for which fetal surgery may be performed in the absence of a delivery during the same hospital stay; and (2) the ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes that describe fetal abnormalities for which fetal surgery may be performed with a subsequent delivery during the same hospital stay. This second concept is the structure of current MS–DRG 768. Commenters should submit their code recommendations for these concepts to the following email address *MSDRGClassificationChange@cms.hhs.gov* by December 7, 2016. We encourage public comments as we consider these enhancements for the FY 2018 ICD–10 MS–DRGs Version 35.

(2) Other Heart Revascularization

In the ICD–9–CM MS–DRGs Version 32, revascularization procedures that are performed to restore blood flow to the heart are identified with procedure code 36.39 (Other heart revascularization). This procedure code is designated as an O.R. procedure and is assigned to MDC 5 (Diseases and Disorders of the Circulatory System) in MS–DRGs 228 through 230 (Other Cardiothoracic Procedures with MCC, with CC, and without CC/MCC, respectively).

A replication issue for 16 ICD–10–PCS comparable code translations that describe revascularization procedures was identified after implementation of the ICD–10 MS–DRGs Version 33. These 16 procedure codes were inadvertently omitted from the MDC 5 GROUPER logic for ICD–10 MS–DRGs 228 through 230. We note that, as discussed in section II.F.5.d. of the preamble of this proposed rule, we are proposing to delete MS–DRG 230 and revise MS–DRG 229. Accordingly, to resolve this replication issue, we are proposing to add the 16 ICD–10–PCS procedure codes listed in the table below to MDC 5 in MS–DRG 228 and proposed revised MS–DRG 229.

ICD–10–PCS procedure code	Description
0210344	Bypass coronary artery, one site from coronary vein with drug-eluting intraluminal device, percutaneous approach.
02103D4	Bypass coronary artery, one site from coronary vein with intraluminal device, percutaneous approach.
0210444	Bypass coronary artery, one site from coronary vein with drug-eluting intraluminal device, percutaneous endoscopic approach.
02104D4	Bypass coronary artery, one site from coronary vein with intraluminal device, percutaneous endoscopic approach.
0211344	Bypass coronary artery, two sites from coronary vein with drug-eluting intraluminal device, percutaneous approach.
02113D4	Bypass coronary artery, two sites from coronary vein with intraluminal device, percutaneous approach.
0211444	Bypass coronary artery, two sites from coronary vein with drug-eluting intraluminal device, percutaneous endoscopic approach.
02114D4	Bypass coronary artery, two sites from coronary vein with intraluminal device, percutaneous endoscopic approach.
0212344	Bypass coronary artery, three sites from coronary vein with drug-eluting intraluminal device, percutaneous approach.
02123D4	Bypass coronary artery, three sites from coronary vein with intraluminal device, percutaneous approach.
0212444	Bypass coronary artery, three sites from coronary vein with drug-eluting intraluminal device, percutaneous endoscopic approach.
02124D4	Bypass coronary artery, three sites from coronary vein with intraluminal device, percutaneous endoscopic approach.
0213344	Bypass coronary artery, four or more sites from coronary vein with drug-eluting intraluminal device, percutaneous approach.
02133D4	Bypass coronary artery, four or more sites from coronary vein with intraluminal device, percutaneous approach.
0213444	Bypass coronary artery, four or more sites from coronary vein with drug-eluting intraluminal device, percutaneous endoscopic approach.
02134D4	Bypass coronary artery, four or more sites from coronary vein with intraluminal device, percutaneous endoscopic approach.

We are inviting public comments on our proposal to add the above listed ICD–10–PCS procedure codes to MDC 5 in MS–DRG 228 and proposed revised MS–DRG 229 (Other Cardiothoracic Procedures with and without MCC, respectively), effective October 1, 2016, in ICD–10 MS–DRGs Version 34.

(3) Procedures on Vascular Bodies: Chemoreceptors

In the ICD–9–CM MS–DRGs Version 32, procedures performed on the sensory receptors are identified with ICD–9–CM procedure code 39.89 (Other operations on carotid body, carotid sinus and other vascular bodies). This procedure code is designated as an O.R. procedure and is assigned to MDC 5 (Diseases and Disorders of the Circulatory System) in MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively).

A replication issue for 234 ICD–10–PCS comparable code translations that describe these procedures was identified after implementation of the ICD–10 MS–DRGs Version 33. These 234 procedure codes were inadvertently omitted from the MDC 5 GROUPER logic for ICD–10 MS–DRGs 252 through 254. To resolve this replication issue, we are proposing to add the 234 ICD–10–PCS procedure codes listed in Table 6P.3b. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*) to MDC 5 in MS–DRG 252, 253, and 254, effective October 1, 2016, in ICD–10 MS–DRGs Version 34. We are inviting public comments on our proposal.

(4) Repair of the Intestine

In the ICD–9–CM MS–DRGs Version 32, the procedure for a repair to the intestine may be identified with procedure code 46.79 (Other repair of intestine). This procedure code is designated as an O.R. procedure and is assigned to MDC 6 (Diseases and Disorders of the Digestive System) in MS–DRGs 329, 330, and 331 (Major Small and Large Bowel Procedures with MCC, with CC, and without CC/MCC, respectively).

A replication issue for four ICD–10–PCS comparable code translations was identified after implementation of the ICD–10 MS–DRGs Version 33. These four procedure codes are:

- 0DQF0ZZ (Repair right large intestine, open approach);
- 0DQG0ZZ (Repair left large intestine, open approach);
- 0DQL0ZZ (Repair transverse colon, open approach); and
- 0DQM0ZZ (Repair descending colon, open approach).

These four ICD–10–PCS codes were inadvertently omitted from the MDC 6 GROUPER logic for ICD–10 MS–DRGs 329 through 331. To resolve this replication issue, we are proposing to add the four ICD–10–PCS procedure codes to MDC 6 in MS–DRG 329, 230, and 331, effective October 1, 2016, in ICD–10 MS–DRGs Version 34. We are inviting public comments on our proposal.

(5) Insertion of Infusion Pump

In the ICD–9–CM MS–DRGs Version 32, the procedure for insertion of an infusion pump is identified with procedure code 86.06 (Insertion of totally implantable infusion pump), which is designated as an O.R. procedure and assigned to a number of MDCs and MS–DRGs across various body systems. We refer readers to the ICD–9–CM MS–DRG Definitions Manual Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index, which is available on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Rule-Data-Files.html*, for the complete list of MDCs and MS–DRGs to which procedure code 86.06 is assigned

A replication issue for 16 ICD–10–PCS comparable code translations was identified after implementation of the ICD–10 MS–DRGs Version 33. These 16 procedure codes are listed in the table below:

ICD–10–PCS procedure code	Description
0JHD0VZ	Insertion of infusion pump into right upper arm subcutaneous tissue and fascia, open approach.
0JHD3VZ	Insertion of infusion pump into right upper arm subcutaneous tissue and fascia, percutaneous approach.
0JHF0VZ	Insertion of infusion pump into left upper arm subcutaneous tissue and fascia, open approach.
0JHF3VZ	Insertion of infusion pump into left upper arm subcutaneous tissue and fascia, percutaneous approach.
0JHG0VZ	Insertion of infusion pump into right lower arm subcutaneous tissue and fascia, open approach.
0JHG3VZ	Insertion of infusion pump into right lower arm subcutaneous tissue and fascia, percutaneous approach.
0JHH0VZ	Insertion of infusion pump into left lower arm subcutaneous tissue and fascia, open approach.
0JHH3VZ	Insertion of infusion pump into left lower arm subcutaneous tissue and fascia, percutaneous approach.
0JHL0VZ	Insertion of infusion pump into right upper leg subcutaneous tissue and fascia, open approach.
0JHL3VZ	Insertion of infusion pump into right upper leg subcutaneous tissue and fascia, percutaneous approach.
0JHM0VZ	Insertion of infusion pump into left upper leg subcutaneous tissue and fascia, open approach.
0JHM3VZ	Insertion of infusion pump into left upper leg subcutaneous tissue and fascia, percutaneous approach.
0JHN0VZ	Insertion of infusion pump into right lower leg subcutaneous tissue and fascia, open approach.
0JHN3VZ	Insertion of infusion pump into right lower leg subcutaneous tissue and fascia, percutaneous approach.
0JHP0VZ	Insertion of infusion pump into left lower leg subcutaneous tissue and fascia, open approach.
0JHP3VZ	Insertion of infusion pump into left lower leg subcutaneous tissue and fascia, percutaneous approach.

These codes were inadvertently omitted from the MDCs and MS–DRGs to which they should be assigned (consistent with the assignment of ICD–9–CM procedure code 86.06) to accurately replicate the ICD–9–CM MS–DRG logic. To resolve this replication issue, we are proposing to add the 16 ICD–10–PCS procedure codes listed above to the corresponding MDCs and MS–DRGs, as set forth in the ICD–9–CM MS–DRG Definitions Manual—Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as described earlier, effective October 1, 2016, in ICD–10 MS–DRGs Version 34. We are inviting public comments on our proposal.

(6) Procedures on the Bursa

In the ICD–9–CM MS–DRGs Version 32, procedures that involve cutting into the bursa are identified with procedure code 83.03 (Bursotomy). This procedure code is designated as an O.R. procedure and is assigned to MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) in MS–DRGs 500, 501, and 502 (Soft Tissue Procedures with MCC, with CC, and without CC/MCC, respectively).

A replication issue for six ICD–10–PCS comparable code translations was identified after implementation of the ICD–10 MS–DRGs Version 33. These six procedure codes are:

- 0M850ZZ (Division of right wrist bursa and ligament, open approach);
- 0M853ZZ (Division of right wrist bursa and ligament, percutaneous approach);
- 0M854ZZ (Division of right wrist bursa and ligament, percutaneous endoscopic approach);
- 0M860ZZ (Division of left wrist bursa and ligament, open approach);
- 0M863ZZ (Division of left wrist bursa and ligament, percutaneous approach); and
- 0M864ZZ (Division of left wrist bursa and ligament, percutaneous endoscopic approach).

These codes were inadvertently omitted from the MDC 8 GROUPER logic for ICD–10 MS–DRGs 500, 501, and 502. To resolve this replication issue, we are proposing to add the six ICD–10–PCS procedure codes listed above to MDC 8 in MS–DRGs 500, 501, and 502, effective October 1, 2016, in ICD–10 MS–DRGs Version 34. We are inviting public comments on our proposal.

(7) Procedures on the Breast

In the ICD–9–CM MS–DRGs Version 32, procedures performed for a simple repair to the skin of the breast may be identified with procedure code 86.59 (Closure of skin and subcutaneous tissue of other sites). This procedure code is designated as a non-O.R. procedure. Therefore, this procedure code does not have an impact on MS–DRG assignment.

A replication issue for two ICD–10–PCS comparable code translations was identified after implementation of the ICD–10 MS–DRGs Version 33. These two procedure codes are: 0HQVXZZ (Repair bilateral breast, external approach) and 0HQYXZZ (Repair supernumerary breast, external approach). These ICD–10–PCS procedures codes were inadvertently assigned to ICD–10 MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC, respectively) in the ICD–10 MS–DRG GROUPER logic. To resolve this replication issue, we are proposing to remove these two ICD–10–PCS procedure codes from MS–DRG 981, 982, and 983, to designate them as non-O.R. procedures, effective October 1, 2016, in ICD–10 MS–DRGs Version 34. We are inviting public comments on our proposal.

(8) Excision of Subcutaneous Tissue and Fascia

In the ICD–9–CM MS–DRGs Version 32, procedures involving excision of the skin and subcutaneous tissue are identified with procedure code 86.3 (Other local excision of lesion or tissue of skin and subcutaneous tissue). This procedure code is designated as a non-O.R. procedure that affects MS–DRG assignment for MS–DRGs 579, 580, and 581 (Other Skin, Subcutaneous Tissue and Breast Procedures with MCC, with CC and without CC/MCC, respectively) in MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast).

A replication issue for 19 ICD–10–PCS comparable code translations was identified after implementation of the ICD–10 MS–DRGs Version 33. These 19 procedure codes are listed in the table below:

ICD–10–PCS code	Description
0JB03ZZ	Excision of scalp subcutaneous tissue and fascia, percutaneous approach.
0JB43ZZ	Excision of anterior neck subcutaneous tissue and fascia, percutaneous approach.
0JB53ZZ	Excision of posterior neck subcutaneous tissue and fascia, percutaneous approach.
0JB63ZZ	Excision of chest subcutaneous tissue and fascia, percutaneous approach.
0JB73ZZ	Excision of back subcutaneous tissue and fascia, percutaneous approach.
0JB83ZZ	Excision of abdomen subcutaneous tissue and fascia, percutaneous approach.
0JB93ZZ	Excision of buttock subcutaneous tissue and fascia, percutaneous approach.
0JBB3ZZ	Excision of perineum subcutaneous tissue and fascia, percutaneous approach.
0JBC3ZZ	Excision of pelvic region subcutaneous tissue and fascia, percutaneous approach.
0JBD3ZZ	Excision of right upper arm subcutaneous tissue and fascia, percutaneous approach.
0JBF3ZZ	Excision of left upper arm subcutaneous tissue and fascia, percutaneous approach.
0JBG3ZZ	Excision of right lower arm subcutaneous tissue and fascia, percutaneous approach.
0JBH3ZZ	Excision of left lower arm subcutaneous tissue and fascia, percutaneous approach.
0JBL3ZZ	Excision of right upper leg subcutaneous tissue and fascia, percutaneous approach.
0JBM3ZZ	Excision of left upper leg subcutaneous tissue and fascia, percutaneous approach.
0JBN3ZZ	Excision of right lower leg subcutaneous tissue and fascia, percutaneous approach.
0JBP3ZZ	Excision of left lower leg subcutaneous tissue and fascia, percutaneous approach.
0JBQ3ZZ	Excision of right foot subcutaneous tissue and fascia, percutaneous approach.
0JBR3ZZ	Excision of left foot subcutaneous tissue and fascia, percutaneous approach.

These codes were inadvertently omitted from the ICD–10 MS–DRG GROUPER logic for MDC 9 in MS–DRGs 579, 580, and 581. To resolve this replication issue, we are proposing to add the 19 ICD–10–PCS procedure codes listed in the table above to MDC 9 in MS–DRGs 579, 580, and 581, effective October 1, 2016, in ICD–10 MS–DRGs Version 34. We are inviting public comments on our proposal.

(9) Shoulder Replacement

In the ICD–9–CM MS–DRGs Version 32, procedures that involve replacing a component of bone from the upper arm are identified with procedure code 78.42 (Other repair or plastic operations on bone, humerus). This procedure code is designated as an O.R. procedure and is assigned to MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) in MS–DRGs 492, 493, and 494 (Lower Extremity and Humerus Procedures Except Hip, Foot and Femur with MCC, with CC, and without CC/MCC, respectively).

A replication issue for two ICD–10–PCS comparable code translations was identified after implementation of the ICD–10 MS–DRGs Version 33. These two procedure codes are: 0PRC0JZ (Replacement of right humeral head with synthetic substitute, open approach) and 0PRD0JZ (Replacement of left humeral head with synthetic substitute, open approach). These two codes were inadvertently omitted from the ICD–10 MS–DRG GROUPER logic for MDC 8 in MS–DRGs 492, 493, and 494. To resolve this replication issue, we are proposing to add these two ICD–10–PCS procedure codes to MDC 8 in MS–DRGs 492, 493, and 494, effective October 1, 2016, in ICD–10 MS–DRGs Version 34. We are inviting public comments on our proposal.

(10) Reposition

In the ICD–9–CM MS–DRGs Version 32, procedures that involve the percutaneous repositioning of an area in the vertebra are identified with procedure code 81.66 (Percutaneous vertebral augmentation). This procedure code is designated as an O.R. procedure and is assigned to MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) in MS–DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue Procedures with MCC, with CC, and without CC/MCC, respectively).

A replication issue for four ICD–10–PCS comparable code translations was identified after implementation of the ICD–10 MS–DRGs Version 33. These four procedure codes are:

- 0PS33ZZ (Reposition cervical vertebra, percutaneous approach);
- 0PS43ZZ (Reposition thoracic vertebra, percutaneous approach);
- 0QS03ZZ (Reposition lumbar vertebra, percutaneous approach); and
- 0QS13ZZ (Reposition sacrum, percutaneous approach).

These four ICD–10PCS procedure codes were inadvertently omitted from the ICD–10 MS–DRG GROUPER logic for MDC 8 and MS–DRGs 515, 516, and 517. To resolve this replication issue, we are proposing to add these four ICD–10–PCS procedure codes to MDC 8 in MS–DRGs 515, 516, and 517, effective October 1, 2016, in ICD–10 MS–DRGs Version 34. We are inviting public comments on our proposal.

(11) Insertion of Infusion Device

In the ICD–9–CM MS–DRGs Version 32, the procedure for insertion of an infusion pump is identified with procedure code 86.06 (Insertion of totally implantable infusion pump) which is designated as an O.R. procedure and assigned to a number of MDCs and MS–DRGs, one of which is MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) in MS–DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC, and without CC/MCC, respectively).

A replication issue for 49 ICD–10–PCS comparable code translations that describe insertion of an infusion device into a joint or disc was identified after implementation of the ICD–10 MS–DRGs Version 33. These 49 procedure codes appear to describe procedures that utilize a specific type of infusion device known as an infusion pump and were inadvertently omitted from the ICD–10 MS–DRG GROUPER logic for MDC 8. To resolve this replication issue, we are proposing to add the 49 ICD–10–PCS procedure codes shown in Table 6P.3c. (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*) to MDC 8 in MS–DRGs 515, 516, and 517, effective October 1, 2016, in ICD–10 MS–DRGs Version 34. We are inviting public comments on our proposal.

(12) Bladder Neck Repair

In the ICD–9–CM MS–DRGs Version 32, a procedure involving a bladder repair is identified with procedure code 57.89 (Other repair of bladder) which is designated as an O.R. procedure and assigned to MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract) in MS–DRGs 653, 654, and 655 (Major Bladder Procedures with MCC, with CC, and without CC/MCC, respectively) and MDC 13 (Diseases and Disorders of the Female Reproductive System) in MS–DRGs 749 and 750 (Other Female Reproductive System O.R. Procedures with CC/MCC and without CC/MCC, respectively).

A replication issue for five ICD–10–PCS comparable code translations that describe a bladder neck repair was identified after implementation of the ICD–10 MS–DRGs Version 33. These five procedure codes are:

- 0TQC0ZZ (Repair Bladder Neck, Open Approach);
- 0TQC3ZZ (Repair Bladder Neck, Percutaneous Approach);
- 0TQC4ZZ (Repair Bladder Neck, Percutaneous Endoscopic Approach);
- 0TQC7ZZ (Repair Bladder Neck, Via Natural or Artificial Opening); and
- 0TQC8ZZ (Repair Bladder Neck, Via Natural or Artificial Opening Endoscopic).

These five ICD–10–PCS procedure codes were inadvertently omitted from the ICD–10 MS–DRG GROUPER logic for MDC 11 in MS–DRGs 653, 654, and 655 and MDC 13 in MS–DRGs 749 and 750. To resolve this replication issue, we are proposing to add these five ICD–10–PCS procedure codes to MDC 11 in MS–DRGs 653, 654, and 655 and MDC 13 in MS–DRGs 749 and 750, effective October 1, 2016, in ICD–10 MS–DRGs Version 34. We are inviting public comments on our proposal.

(13) Future Consideration

We note that commenters have suggested that there are a number of procedure codes that may not appear to be clinically feasible due to a specific approach or device value in relation to a unique body part in a given body system. These commenters have not identified a comprehensive list of codes to be deleted. However, they have suggested that CMS examine these codes further. Due to the multiaxial structure of ICD–10–PCS, the current system allows for multiple possibilities for a given procedure, some of which may not currently be used. As our focus to refine the ICD–10 MS–DRGs continues, for FY 2018, we will begin to conduct an analysis of where such ICD–10–PCS codes may exist. We welcome suggestions from the public of code refinements that could address the issue of current ICD–10–PCS codes that capture procedures that would not reasonably be performed. Commenters should submit their recommendations for these code refinements to the following email address: *MSDRGClassificationChanges@cms.hhs.gov* by December 7, 2016.

We also note that any suggestions that are received by December 7, 2016 to update ICD–10–PCS, including creating new codes or deleting existing codes, will be addressed by the ICD–10 Coordination and Maintenance Committee. Proposals to address the modification of any ICD–10–PCS codes are discussed at the ICD–10 Coordination and Maintenance Committee meetings held in March and September of each year. We refer the reader to section II.F.17. of the preamble of this proposed rule for information related to this process to request updates to ICD–10–PCS.

b. Issues Relating to MS–DRG 999 (Ungroupable)

Under the ICD–9–CM MS–DRGs Version 32, a diagnosis of complications of an obstetric surgical wound after delivery is identified with diagnosis code 674.32 (Other complications of obstetrical surgical wounds, delivered, with mention of postpartum complication) and is assigned to MDC 14 (Pregnancy, Childbirth and the Puerperium) under MS–DRG 769 (Postpartum and Post Abortion Diagnoses with O.R. Procedure) or MS–DRG 776 (Postpartum and Post Abortion Diagnoses without O.R. Procedure). A replication issue under the ICD–10 MS–DRGs Version 33 for this condition was identified after implementation on October 1, 2015. Under ICD–10–CM, diagnosis code O90.2 (Hematoma of obstetric wound) is the comparable translation for ICD–9–CM diagnosis code 674.32. We discovered that cases where a patient has been readmitted to the hospital after a delivery and ICD–10–CM diagnosis code O90.2 is reported as the principal diagnosis are resulting in assignment to MS–DRG 999 (Ungroupable).

In the ICD–9–CM diagnosis code description, the concept of "delivery" is included in the code title. This concept is not present in the ICD–10–CM classification and has led to a replication issue for patients who delivered during a previous stay and are subsequently readmitted for the complication. To resolve this replication issue, we are proposing to add ICD–10–CM diagnosis code O90.2 to MDC 14 under MS–DRGs 769 and 776. This refinement would be consistent with the ICD–9–CM diagnosis code assignment and result in a more accurate replication of the ICD–9–CM MS–DRGs Version 32.

We are inviting public comments on our proposal to add ICD–10–CM diagnosis code O90.2 to MS–DRG 769 and MS–DRG 776 in MDC 14, effective October 1, 2016, in the ICD–10 MS–DRGs Version 34.

c. Other Operating Room (O.R.) and Non-O.R. Issues

(1) O.R. Procedures to Non-O.R. Procedures

For this FY 2017 IPPS/LTCH PPS proposed rule, we continued our efforts to address the MS–DRG replication issues between ICD–9–CM logic and ICD–10 that were brought to our attention. As a result of analyzing those specific requests, we identified areas in the ICD–10–PCS classification where additional refinements could further support our replication efforts. We discuss these below.

We evaluated specific groups of ICD–10–PCS procedure codes with respect to their current operating room (O.R.) designation that were determined to be inconsistent with the ICD–9–CM procedure codes from which the designation was initially derived. Our review demonstrated that these ICD–10–PCS procedure codes should instead have the attributes of a more logical ICD–9–CM procedure code translation for MS–DRG replication purposes. As specified below, we are proposing to change the status of ICD–10–PCS procedure codes from being designated as O.R. to non-O.R. for the ICD–10 MS–DRGs Version 34. For each group summarized below, the detailed code lists are shown in Tables 6P.4a. through 6P.4k. (ICD–10–CM and ICD–10–PCS Codes for Proposed MCE and MS–DRG Changes—FY 2017) associated with this proposed rule, which are available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

(a) Endoscopic/Transorifice Insertion

We found 72 ICD–10–PCS procedure codes describing an endoscopic/transorifice (via natural or artificial opening) insertion of infusion and monitoring devices into various tubular body parts that, when coded under ICD–9–CM, would reasonably correlate to other noninvasive catheterization and monitoring types of procedure codes versus an "incision of [body part]" or "other operation on a [body part]" procedure code. We are proposing that the 72 ICD–10–PCS procedure codes in Table 6P.4a. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/*

Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html) be assigned the attributes of the ICD–9–CM procedure code specified in column C. The ICD–9–CM procedure codes and descriptions in column C would replace the ICD–9–CM procedure codes and descriptions reflected in column D, which are considered less accurate correlations. We are inviting public comments on this proposal.

(b) Endoscopic/Transorifice Removal

We found 155 ICD–10–PCS procedure codes describing an endoscopic/transorifice (via natural or artificial opening) removal of common devices such as a drainage device, infusion device, intraluminal device, or monitoring device from various tubular body parts that, when coded under ICD–9–CM, would reasonably correlate to other nonoperative removal of a wide range of devices/appliances procedure codes versus an "incision of [body part]" or "other operation on a [body part]" procedure code. We are proposing that the 155 ICD–10–PCS procedure codes in Table 6P.4b. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be assigned the attributes of the ICD–9–CM procedure code specified in column C. The ICD–9–CM procedure codes and descriptions in column C would replace the ICD–9–CM procedure codes and descriptions reflected in column D, which are considered less accurate correlations. We are inviting public comments on this proposal.

(c) Tracheostomy Device Removal

We found five ICD–10–PCS procedure codes describing removal of a tracheostomy device with various approaches such that, when coded under ICD–9–CM, would reasonably correlate to the nonoperative removal of a tracheostomy device procedure code versus an "incision of [body part]" or "other operation on a [body part]" procedure code. We acknowledge that, under ICD–10–PCS, an "open" approach is defined as "cutting through." However, this procedure was designated as non-O.R. under ICD–9–CM. For replication purposes, we are proposing that the five ICD–10–PCS procedure codes in Table 6P.4c. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be assigned the attributes of the ICD–9–CM procedure code specified in column C. The ICD–9–CM procedure codes and descriptions in column C would replace the ICD–9–CM procedure codes and descriptions reflected in column D, which are considered less accurate correlations. We are inviting public comments on this proposal.

(d) Endoscopic/Percutaneous Insertion

We found 117 ICD–10–PCS procedure codes describing the endoscopic/percutaneous insertion of infusion and monitoring devices into vascular and musculoskeletal body parts that, when coded under ICD–9–CM, would reasonably correlate to other noninvasive catheterization and monitoring types of procedure codes versus an "incision of [body part]" or "other operation on a [body part]" procedure code. We are proposing that the 117 ICD–10–PCS procedure codes in Table 6P.4d. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* be assigned the attributes of the ICD–9–CM procedure code specified in column C. The ICD–9–CM procedure codes and descriptions in column C would replace the ICD–9–CM procedure codes and descriptions reflected in column D, which are less accurate correlations. We are inviting public comments on this proposal.

(e) Percutaneous Removal

We found 124 ICD–10–PCS procedure codes describing the percutaneous removal of drainage, infusion and monitoring devices from vascular and musculoskeletal body parts that, when coded under ICD–9–CM, would reasonably correlate to the nonoperative removal of a wide range of devices/appliances procedure codes versus an "incision of [body part]" or "other operation on a [body part]" procedure code. We are proposing that the 124 ICD–10–PCS procedure codes in Table 6P.4e. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be assigned the attributes of the ICD–9–CM procedure code specified in column C. The ICD–9–CM procedure codes and descriptions in column C would replace the ICD–9–CM procedure codes and descriptions reflected in column D, which are considered less accurate correlations. We are inviting public comments on this proposal.

(f) Percutaneous Drainage

We found 518 ICD–10–PCS procedure codes describing the percutaneous therapeutic drainage of all body sites that do not have specific percutaneous drainage codes. The list includes procedure codes for drainage with or without placement of a drainage device. Exceptions to this are cranial, intracranial and the eye where small incisions are the norm and appropriately classified as O.R. These 518 ICD–10–PCS procedures codes, when coded under ICD–9–CM, would reasonably correlate to the nonoperative puncture or drainage of various body sites and other miscellaneous procedures versus an "incision of [body part]" procedure code. We are proposing that the 518 ICD–10–PCS procedure codes in Table 6P.4f. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be assigned the attributes of the ICD–9–CM procedure code specified in column C. The ICD–9–CM procedure codes and descriptions in column C would replace the ICD–9–CM procedure codes and descriptions reflected in column D, which are considered less accurate correlations. We are inviting public comments on this proposal.

(g) Percutaneous Inspection

We found 131 ICD–10–PCS procedure codes describing the percutaneous inspection of body part sites, with the exception of the cranial cavity and brain, whose designation is not consistent with other percutaneous inspection codes. When coded under ICD–9–CM, these procedure codes would reasonably correlate to the "other nonoperative examinations" and "other diagnostic procedures on [body part]" codes where the approach is not specified and the codes are designated as non-O.R. We are proposing that the 131 ICD–10–PCS procedure codes in Table 6P.4g. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be assigned the attributes of the ICD–9–CM procedure code specified in column C. The ICD–9–CM procedure codes and descriptions in column C would replace the ICD–9–CM procedure codes and descriptions reflected in column D, which are considered less accurate correlations. We are inviting public comments on this proposal.

(h) Inspection Without Incision

We found 40 ICD–10–PCS procedure codes describing the inspection of various body sites with endoscopic/transorifice and external approaches. Under ICD–9–CM, these codes would reasonably correlate to "other diagnostic procedures on [body part]" codes where the approach is not specified and the codes are designated as non-O.R. We are proposing that the 40 ICD–10–PCS codes in Table 6P.4h. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be assigned the attributes of the ICD–9–CM code specified in column C. The ICD–9–CM codes and descriptions in column C would replace the ICD–9–CM codes and descriptions reflected in column D, which are considered less accurate correlations. We are inviting public comments on this proposal.

(i) Dilation of Stomach

We found six ICD–10–PCS procedure codes describing the dilation of stomach and pylorus body sites with various approaches whose designation is not consistent with all other gastrointestinal body parts dilation codes. Under ICD–9–CM, where a unique dilation code exists, the approach is not specified and these codes are designated as non-O.R. Therefore, we are proposing that the six ICD–10–PCS procedure codes in Table 6P.4i. (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be assigned the attributes of the ICD–9–CM code specified in column C. The ICD–9–CM codes and descriptions in column C would replace the ICD–9–CM codes and descriptions reflected in column D, which are considered less accurate correlations. We are inviting public comments on this proposal.

(j) Endoscopic/Percutaneous Occlusion

We found six ICD–10–PCS codes describing percutaneous occlusion of esophageal vein with and without a device that, when coded under ICD–9–CM would reasonably correlate to the endoscopic excision or destruction of the vessel versus an open surgical procedure. We are proposing that the six ICD–10–PCS procedure codes in Table 6P.4j. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be assigned the attributes of the ICD–9–CM code specified in column C. The ICD–9–CM codes and descriptions in column C would replace the ICD–9–CM codes and descriptions reflected in column D, which are considered less accurate correlations. We are inviting public comments on this proposal.

(k) Infusion Device

We found 82 ICD–10–PCS codes describing the insertion of an infusion device to various body parts that, when coded under ICD–9–CM, would reasonably correlate to the insertion of a common infusion catheter versus the insertion of a totally implantable infusion pump. We are proposing that the 82 ICD–10–PCS procedure codes in Table 6P.4k. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*) be assigned the attributes of the ICD–9–CM code specified in column C. The ICD–9–CM codes and descriptions in column C would replace the ICD–9–CM codes and descriptions reflected in column D, which are considered less accurate correlations. We are inviting public comments on this proposal.

(2) Non-O.R. Procedures to O.R. Procedures

(a) Drainage of Pleural Cavity

In the ICD–9–CM MS–DRGs Version 32 Definitions Manual under Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index, procedure code 34.06 (Thoracoscopic drainage of pleural cavity) is designated as an O.R. procedure code and is assigned to MS–DRGs 166 through 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 4 (Diseases and Disorders of the Respiratory System).

A replication issue regarding the procedure code designation and MS–DRG assignment for the comparable code translations under the ICD–10 MS–DRGs Version 33 was brought to our attention after implementation on October 1, 2015. The replication issue involves the following four ICD–10–PCS procedure codes:

- 0W9940Z (Drainage of right pleural cavity with drainage device, percutaneous endoscopic approach);
- 0W994ZZ (Drainage of right pleural cavity, percutaneous endoscopic approach);
- 0W9B40Z (Drainage of left pleural cavity with drainage device, percutaneous endoscopic approach); and
- 0W9B4ZZ (Drainage of left pleural cavity, percutaneous endoscopic approach).

In the ICD–10 MS–DRGs Version 33, these four ICD–10–PCS procedure codes are not recognized as O.R. procedures for purposes of MS–DRG assignment. We agree that this was a replication error and the designation and MS–DRG assignment should be consistent with the designation and MS–DRG assignment of ICD–9–CM procedure code 34.06.

To resolve this replication issue, we are proposing to add ICD–10–PCS procedure codes 0W9940Z, 0W994ZZ, 0W9B40Z, and 0W9B4ZZ to the FY 2017 ICD–10 MS–DRGs Version 34 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures assigned to MS–DRGs 166 through 168 in MDC 4. We are inviting public comments on our proposal.

(b) Drainage of Cerebral Ventricle

In the ICD–9–CM MS–DRGs Version 32 Definitions Manual under Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index, procedure code 02.22 (Intracranial ventricular shunt or anastomosis) is designated as an O.R. procedure code and is assigned to MS–DRGs 023 through 027, collectively referred to as the "Craniotomy" MS–DRGs, in MDC 1 (Diseases and Disorders of the Nervous System).

A replication issue regarding the procedure code designation and MS–DRG assignment for the comparable code translations under the ICD–10 MS–DRGs Version 33 was brought to our attention after implementation on October 1, 2015. The replication issue involves the following ICD–10–PCS procedure codes:

ICD–10–PCS procedure code	Description
009130Z	Drainage of cerebral meninges with drainage device, percutaneous approach.
00913ZZ	Drainage of cerebral meninges, percutaneous approach.
009140Z	Drainage of cerebral meninges with drainage device, percutaneous endoscopic approach.

ICD–10–PCS procedure code	Description
00914ZZ	Drainage of cerebral meninges with drainage device, percutaneous endoscopic approach.
009230Z	Drainage of dura mater with drainage device, percutaneous approach.
00923ZZ	Drainage of dura mater, percutaneous approach.
009240Z	Drainage of dura mater with drainage device, percutaneous endoscopic approach.
00924ZZ	Drainage of dura mater, percutaneous endoscopic approach.
009430Z	Drainage of subdural space with drainage device, percutaneous approach.
00943ZZ	Drainage of subdural space, percutaneous approach.
009440Z	Drainage of subdural space with drainage device, percutaneous endoscopic approach.
00944ZZ	Drainage of subdural space, percutaneous endoscopic approach.
009530Z	Drainage of subarachnoid space with drainage device, percutaneous approach.
00953ZZ	Drainage of subarachnoid space, percutaneous approach.
009540Z	Drainage of subarachnoid space with drainage device, percutaneous endoscopic approach.
00954ZZ	Drainage of subarachnoid space, percutaneous endoscopic approach.
00963ZZ	Drainage of cerebral ventricle, percutaneous approach.
00964ZZ	Drainage of cerebral ventricle, percutaneous endoscopic approach.

In the ICD–10 MS–DRGs Version 33, these ICD–10–PCS procedure codes are not recognized as O.R. procedures for purposes of MS–DRG assignment. We agree that this was a replication error and their translation should be consistent with the designation and MS–DRG assignment of ICD–9–CM procedure 02.22.

To resolve this replication issue, we are proposing to add the ICD–10–PCS procedure codes listed above to the FY 2017 ICD–10 MS–DRGs Version 34 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures assigned to MS–DRGs 023 through 027 in MDC 1. We are inviting public comments on our proposal.

G. Recalibration of the Proposed FY 2017 MS–DRG Relative Weights

1. Data Sources for Developing the Relative Weights

In developing the proposed FY 2017 system of weights, we used two data sources: Claims data and cost report data. As in previous years, the claims data source is the MedPAR file. This file is based on fully coded diagnostic and procedure data for all Medicare inpatient hospital bills. The FY 2015 MedPAR data used in this proposed rule include discharges occurring on October 1, 2014, through September 30, 2015, based on bills received by CMS through December 31, 2015, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which at that time were under a waiver from the IPPS). The FY 2015 MedPAR file used in calculating the proposed relative weights includes data for approximately 9,706,869 Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare Advantage managed care plan are excluded from this analysis. These discharges are excluded when the MedPAR "GHO Paid" indicator field on the claim record is equal to "1" or when the MedPAR DRG payment field, which represents the total payment for the claim, is equal to the MedPAR "Indirect Medical Education (IME)" payment field, indicating that the claim was an "IME only" claim submitted by a teaching hospital on behalf of a beneficiary enrolled in a Medicare Advantage managed care plan. In addition, the December 31, 2015 update of the FY 2015 MedPAR file complies with version 5010 of the X12 HIPAA Transaction and Code Set Standards, and includes a variable called "claim type." Claim type "60" indicates that the claim was an inpatient claim paid as fee-for-service. Claim types "61," "62," "63," and "64" relate to encounter claims, Medicare Advantage IME claims, and HMO no-pay claims. Therefore, the calculation of the proposed relative weights for FY 2017 also excludes claims with claim type values not equal to "60." The data exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken. We note that the proposed FY 2017 relative weights are based on the ICD–9–CM diagnoses and procedures codes from the FY 2015 MedPAR claims data, grouped through the ICD–9–CM version of the FY 2017 GROUPER (Version 34).

The second data source used in the cost-based relative weighting methodology is the Medicare cost report data files from the HCRIS. Normally, we use the HCRIS dataset that is 3 years prior to the IPPS fiscal year. Specifically, we used cost report data from the December 31, 2015 update of the FY 2014 HCRIS for calculating the proposed FY 2017 cost-based relative weights.

2. Methodology for Calculation of the Proposed Relative Weights

As we explain in section II.E.2. of the preamble of this proposed rule, we calculated the proposed FY 2017 relative weights based on 19 CCRs, as we did for FY 2016. The methodology we used to calculate the proposed FY 2017 MS–DRG cost-based relative weights based on claims data in the FY 2015 MedPAR file and data from the FY 2014 Medicare cost reports is as follows:

- To the extent possible, all the claims were regrouped using the proposed FY 2017 MS–DRG classifications discussed in sections II.B. and II.F. of the preamble of this proposed rule.
- The transplant cases that were used to establish the relative weights for heart and heart-lung, liver and/or intestinal, and lung transplants (MS–DRGs 001, 002, 005, 006, and 007, respectively) were limited to those Medicare-approved transplant centers that have cases in the FY 2015 MedPAR file. (Medicare coverage for heart, heart-lung, liver and/or intestinal, and lung transplants is limited to those facilities that have received approval from CMS as transplant centers.)
- Organ acquisition costs for kidney, heart, heart-lung, liver, lung, pancreas, and intestinal (or multivisceral organs) transplants continue to be paid on a reasonable cost basis. Because these acquisition costs are paid separately from the prospective payment rate, it is necessary to subtract the acquisition charges from the total charges on each transplant bill that showed acquisition charges before computing the average cost for each MS–DRG and before eliminating statistical outliers.
- Claims with total charges or total lengths of stay less than or equal to zero were deleted. Claims that had an amount in the total charge field that differed by more than $10.00 from the sum of the routine day charges,

intensive care charges, pharmacy charges, special equipment charges, therapy services charges, operating room charges, cardiology charges, laboratory charges, radiology charges, other service charges, labor and delivery charges, inhalation therapy charges, emergency room charges, blood charges, and anesthesia charges were also deleted.

- At least 92.4 percent of the providers in the MedPAR file had charges for 14 of the 19 cost centers. All claims of providers that did not have charges greater than zero for at least 14 of the 19 cost centers were deleted. In other words, a provider must have no more than five blank cost centers. If a provider did not have charges greater than zero in more than five cost centers, the claims for the provider were deleted.
- Statistical outliers were eliminated by removing all cases that were beyond 3.0 standard deviations from the geometric mean of the log distribution of both the total charges per case and the total charges per day for each MS–DRG.
- Effective October 1, 2008, because hospital inpatient claims include a POA indicator field for each diagnosis present on the claim, only for purposes of relative weight-setting, the POA indicator field was reset to "Y" for "Yes" for all claims that otherwise have an "N" (No) or a "U" (documentation insufficient to determine if the condition was present at the time of inpatient admission) in the POA field.

Under current payment policy, the presence of specific HAC codes, as indicated by the POA field values, can generate a lower payment for the claim. Specifically, if the particular condition is present on admission (that is, a "Y" indicator is associated with the diagnosis on the claim), it is not a HAC, and the hospital is paid for the higher severity (and, therefore, the higher weighted MS–DRG). If the particular condition is not present on admission (that is, an "N" indicator is associated with the diagnosis on the claim) and there are no other complicating conditions, the DRG GROUPER assigns the claim to a lower severity (and, therefore, the lower weighted MS–DRG) as a penalty for allowing a Medicare inpatient to contract a HAC. While the POA reporting meets policy goals of encouraging quality care and generates program savings, it presents an issue for the relative weight-setting process. Because cases identified as HACs are likely to be more complex than similar cases that are not identified as HACs, the charges associated with HAC cases are likely to be higher as well. Therefore, if the higher charges of these HAC claims are grouped into lower severity MS–DRGs prior to the relative weight-setting process, the relative weights of these particular MS–DRGs would become artificially inflated, potentially skewing the relative weights. In addition, we want to protect the integrity of the budget neutrality process by ensuring that, in estimating payments, no increase to the standardized amount occurs as a result of lower overall payments in a previous year that stem from using weights and case-mix that are based on lower severity MS–DRG assignments. If this would occur, the anticipated cost savings from the HAC policy would be lost.

To avoid these problems, we reset the POA indicator field to "Y" only for relative weight-setting purposes for all claims that otherwise have an "N" or a "U" in the POA field. This resetting "forced" the more costly HAC claims into the higher severity MS–DRGs as appropriate, and the relative weights calculated for each MS–DRG more closely reflect the true costs of those cases.

In addition, in the FY 2013 IPPS/LTCH PPS final rule, for FY 2013 and subsequent fiscal years, we finalized a policy to treat hospitals that participate in the Bundled Payments for Care Improvement (BPCI) initiative the same as prior fiscal years for the IPPS payment modeling and ratesetting process without regard to hospitals' participation within these bundled payment models (that is, as if hospitals were not participating in those models under the BPCI initiative). The BPCI initiative, developed under the authority of section 3021 of the Affordable Care Act (codified at section 1115A of the Act), is comprised of four broadly defined models of care, which link payments for multiple services beneficiaries receive during an episode of care. Under the BPCI initiative, organizations enter into payment arrangements that include financial and performance accountability for episodes of care. For FY 2017, we are proposing to continue to include all applicable data from subsection (d) hospitals participating in BPCI Models 1, 2, and 4 in our IPPS payment modeling and ratesetting calculations. We refer readers to the FY 2013 IPPS/LTCH PPS final rule for a complete discussion on our final policy for the treatment of hospitals participating in the BPCI initiative in our ratesetting process. For additional information on the BPCI initiative, we refer readers to the CMS' Center for Medicare and Medicaid Innovation's Web site at: *http://innovation.cms.gov/initiatives/Bundled-Payments/index.html* and to section IV.H.4. of the preamble of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53341 through 53343).

Once the MedPAR data were trimmed and the statistical outliers were removed, the charges for each of the 19 cost groups for each claim were standardized to remove the effects of differences in area wage levels, IME and DSH payments, and for hospitals located in Alaska and Hawaii, the applicable cost-of-living adjustment. Because hospital charges include charges for both operating and capital costs, we standardized total charges to remove the effects of differences in geographic adjustment factors, cost-of-living adjustments, and DSH payments under the capital IPPS as well. Charges were then summed by MS–DRG for each of the 19 cost groups so that each MS–DRG had 19 standardized charge totals. These charges were then adjusted to cost by applying the national average CCRs developed from the FY 2014 cost report data.

The 19 cost centers that we used in the proposed relative weight calculation are shown in the following table. The table shows the lines on the cost report and the corresponding revenue codes that we used to create the proposed 19 national cost center CCRs. If stakeholders have comments about the groupings in this table, we may consider those comments as we finalize our policy.

Cost center group name (19 total)	MedPAR charge field	Revenue codes contained in MedPAR charge field	Cost report line description	Cost from HCRIS (worksheet C, Part 1, column 5 and line number) form CMS–2552–10	Charges from HCRIS (worksheet C, Part 1, column 6 & 7 and line number) form CMS–2552–10	Medicare charges from HCRIS (worksheet D–3, column & line number) form CMS–2552–10
Routine Days	Private Room Charges.	011X and 014X	Adults & Pediatrics (General Routine Care).	C_1_C5_30	C_1_C6_30	D3_HOS_C2_30

Cost center group name (19 total)	MedPAR charge field	Revenue codes contained in MedPAR charge field	Cost report line description	Cost from HCRIS (worksheet C, Part 1, column 5 and line number) form CMS–2552–10	Charges from HCRIS (worksheet C, Part 1, column 6 & 7 and line number) form CMS–2552–10	Medicare charges from HCRIS (worksheet D–3, column & line number) form CMS–2552–10
	Semi-Private Room Charges.	012X, 013X and 016X–019X.				
	Ward Charges	015X.				
Intensive Days	Intensive Care Charges.	020X	Intensive Care Unit.	C_1_C5_31	C_1_C6_31	D3_HOS_C2_31
	Coronary Care Charges.	021X	Coronary Care Unit.	C_1_C5_32	C_1_C6_32	D3_HOS_C2_32
			Burn Intensive Care Unit.	C_1_C5_33	C_1_C6_33	D3_HOS_C2_33
			Surgical Intensive Care Unit.	C_1_C5_34	C_1_C6_34	D3_HOS_C2_34
			Other Special Care Unit.	C_1_C5_35	C_1_C6_35	D3_HOS_C2_35
Drugs	Pharmacy Charges.	025X, 026X and 063X.	Intravenous Therapy.	C_1_C5_64	C_1_C6_64 C_1_C7_64	D3_HOS_C2_64
			Drugs Charged To Patient.	C_1_C5_73	C_1_C6_73 C_1_C7_73	D3_HOS_C2_73
Supplies and Equipment.	Medical/Surgical Supply Charges.	0270, 0271, 0272, 0273, 0274, 0277, 0279, and 0621, 0622, 0623.	Medical Supplies Charged to Patients.	C_1_C5_71	C_1_C6_71 C_1_C7_71	D3_HOS_C2_71
	Durable Medical Equipment Charges.	0290, 0291, 0292 and 0294-0299.	DME-Rented	C_1_C5_96	C_1_C6_96 C_1_C7_96	D3_HOS_C2_96
	Used Durable Medical Charges.	0293	DME-Sold	C_1_C5_97	C_1_C6_97 C_1_C7_97	D3_HOS_C2_97
Implantable Devices.		0275, 0276, 0278, 0624.	Implantable Devices Charged to Patients.	C_1_C5_72	C_1_C6_72 C_1_C7_72	D3_HOS_C2_72
Therapy Services	Physical Therapy Charges.	042X	Physical Therapy	C_1_C5_66	C_1_C6_66 C_1_C7_66	D3_HOS_C2_66
	Occupational Therapy Charges.	043X	Occupational Therapy.	C_1_C5_67	C_1_C6_67 C_1_C7_67	D3_HOS_C2_67
	Speech Pathology Charges.	044X and 047X	Speech Pathology	C_1_C5_68	C_1_C6_68 C_1_C7_68	D3_HOS_C2_68
Inhalation Therapy	Inhalation Therapy Charges.	041X and 046X	Respiratory Therapy.	C_1_C5_65	C_1_C6_65 C_1_C7_65	D3_HOS_C2_65
Operating Room	Operating Room Charges.	036X	Operating Room	C_1_C5_50	C_1_C6_50 C_1_C7_50	D3_HOS_C2_50
		071X	Recovery Room	C_1_C5_51	C_1_C6_51 C_1_C7_51	D3_HOS_C2_51
Labor & Delivery	Operating Room Charges.	072X	Delivery Room and Labor Room.	C_1_C5_52	C_1_C6_52 C_1_C7_52	D3_HOS_C2_52
Anesthesia	Anesthesia Charges.	037X	Anesthesiology	C_1_C5_53	C_1_C6_53 C_1_C7_53	D3_HOS_C2_53
Cardiology	Cardiology Charges.	048X and 073X	Electro-cardiology	C_1_C5_69	C_1_C6_69 C_1_C7_69	D3_HOS_C2_69
Cardiac Catheterization.		0481	Cardiac Catheterization.	C_1_C5_59	C_1_C6_59 C_1_C7_59	D3_HOS_C2_59
Laboratory	Laboratory Charges.	030X, 031X, and 075X.	Laboratory	C_1_C5_60	C_1_C6_60 C_1_C7_60	D3_HOS_C2_60
			PBP Clinic Laboratory Services.	C_1_C5_61	C_1_C6_61 C_1_C7_61	D3_HOS_C2_61
		074X, 086X	Electro-Encephalography.	C_1_C5_70	C_1_C6_70 C_1_C7_70	D3_HOS_C2_70
Radiology	Radiology Charges.	032X, 040X	Radiology—Diagnostic.	C_1_C5_54	C_1_C6_54 C_1_C7_54	D3_HOS_C2_54
		028x, 0331, 0332, 0333, 0335, 0339, 0342.	Radiology—Therapeutic.	C_1_C5_55	C_1_C6_55	D3_HOS_C2_55
		0343 and 344	Radioisotope	C_1_C5_56	C_1_C6_56 C_1_C7_56	D3_HOS_C2_56
Computed Tomography (CT) Scan.	CT Scan Charges	035X	Computed Tomography (CT) Scan.	C_1_C5_57	C_1_C6_57 C_1_C7_57	D3_HOS_C2_57

Cost center group name (19 total)	MedPAR charge field	Revenue codes contained in MedPAR charge field	Cost report line description	Cost from HCRIS (worksheet C, Part 1, column 5 and line number) form CMS–2552–10	Charges from HCRIS (worksheet C, Part 1, column 6 & 7 and line number) form CMS–2552–10	Medicare charges from HCRIS (worksheet D–3, column & line number) form CMS–2552–10
Magnetic Resonance Imaging (MRI).	MRI Charges	061X	Magnetic Resonance Imaging (MRI).	C_1_C5_58	C_1_C6_58 C_1_C7_58	D3_HOS_C2_58
Emergency Room	Emergency Room Charges.	045x	Emergency	C_1_C5_91	C_1_C6_91 C_1_C7_91	D3_HOS_C2_91
Blood and Blood Products.	Blood Charges	038x	Whole Blood & Packed Red Blood Cells.	C_1_C5_62	C_1_C6_62 C_1_C7_62	D3_HOS_C2_62
	Blood Storage/Processing.	039x	Blood Storing, Processing, & Transfusing.	C_1_C5_63	C_1_C6_63 C_1_C7_63	D3_HOS_C2_63
Other Services	Other Service Charge.	0002–0099, 022X, 023X, 024X, 052X, 053X. 055X–060X, 064X–070X, 076X–078X, 090X–095X and 099X.				
	Renal Dialysis	0800X	Renal Dialysis	C_1_C5_74	C_1_C6_74 C_1_C7_74.	D3_HOS_C2_74
	ESRD Revenue Setting Charges.	080X and 082X–088X.				
			Home Program Dialysis.	C_1_C5_94	C_1_C6_94 C_1_C7_94	D3_HOS_C2_94
	Outpatient Service Charges.	049X	ASC (Non Distinct Part).	C_1_C5_75	C_1_C6_75 C_1_C7_75	D3_HOS_C2_75
	Lithotripsy Charge	079X.				
			Other Ancillary	C_1_C5_76	C_1_C6_76 C_1_C7_76	D3_HOS_C2_76
	Clinic Visit Charges.	051X	Clinic	C_1_C5_90	C_1_C6_90 C_1_C7_90	D3_HOS_C2_90
			Observation beds	C_1_C5_92.01	C_1_C6_92.01 C_1_C7_92.01	D3_HOS_C2_92.01
	Professional Fees Charges.	096X, 097X, and 098X.	Other Outpatient Services.	C_1_C5_93	C_1_C6_93 C_1_C7_93	D3_HOS_C2_93
	Ambulance Charges.	054X	Ambulance	C_1_C5_95	C_1_C6_95 C_1_C7_95	D3_HOS_C2_95
			Rural Health Clinic.	C_1_C5_88	C_1_C6_88 C_1_C7_88	D3_HOS_C2_88
			FQHC	C_1_C5_89	C_1_C6_89 C_1_C7_89	D3_HOS_C2_89

3. Development of National Average CCRs

We developed the national average CCRs as follows:

Using the FY 2014 cost report data, we removed CAHs, Indian Health Service hospitals, all-inclusive rate hospitals, and cost reports that represented time periods of less than 1 year (365 days). We included hospitals located in Maryland because we include their charges in our claims database. We then created CCRs for each provider for each cost center (see prior table for line items used in the calculations) and removed any CCRs that were greater than 10 or less than 0.01. We normalized the departmental CCRs by dividing the CCR for each department by the total CCR for the hospital for the purpose of trimming the data. We then took the logs of the normalized cost center CCRs and removed any cost center CCRs where the log of the cost center CCR was greater or less than the mean log plus/minus 3 times the standard deviation for the log of that cost center CCR. Once the cost report data were trimmed, we calculated a Medicare-specific CCR. The Medicare-specific CCR was determined by taking the Medicare charges for each line item from Worksheet D–3 and deriving the Medicare-specific costs by applying the hospital-specific departmental CCRs to the Medicare-specific charges for each line item from Worksheet D–3. Once each hospital's Medicare-specific costs were established, we summed the total Medicare-specific costs and divided by the sum of the total Medicare-specific charges to produce national average, charge-weighted CCRs.

After we multiplied the total charges for each MS–DRG in each of the 19 cost centers by the corresponding national average CCR, we summed the 19 "costs" across each MS–DRG to produce a total standardized cost for the MS–DRG. The average standardized cost for each MS–DRG was then computed as the total standardized cost for the MS–DRG divided by the transfer-adjusted case count for the MS–DRG. The average cost for each MS–DRG was then divided by the national average standardized cost per case to determine the relative weight.

The proposed FY 2017 cost-based relative weights were then normalized by an adjustment factor of 1.690233 so that the average case weight after recalibration was equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act.

The proposed 19 national average CCRs for FY 2017 are as follows:

Group	CCR
Routine Days	0.459
Intensive Days	0.378
Drugs	0.194
Supplies & Equipment	0.298
Implantable Devices	0.336
Therapy Services	0.322
Laboratory	0.120
Operating Room	0.192
Cardiology	0.113
Cardiac Catheterization	0.119
Radiology	0.154
MRIs	0.079
CT Scans	0.039
Emergency Room	0.172
Blood and Blood Products	0.325
Other Services	0.368
Labor & Delivery	0.411
Inhalation Therapy	0.170
Anesthesia	0.090

Since FY 2009, the relative weights have been based on 100 percent cost weights based on our MS–DRG grouping system.

When we recalibrated the DRG weights for previous years, we set a threshold of 10 cases as the minimum number of cases required to compute a reasonable weight. For FY 2017, we are proposing to use that same case threshold in recalibrating the MS–DRG relative weights for FY 2017. Using data from the FY 2015 MedPAR file, there were 8 MS–DRGs that contain fewer than 10 cases. Under the MS–DRGs, we have fewer low-volume DRGs than under the CMS DRGs because we no longer have separate DRGs for patients aged 0 to 17 years. With the exception of newborns, we previously separated some DRGs based on whether the patient was age 0 to 17 years or age 17 years and older. Other than the age split, cases grouping to these DRGs are identical. The DRGs for patients aged 0 to 17 years generally have very low volumes because children are typically ineligible for Medicare. In the past, we have found that the low volume of cases for the pediatric DRGs could lead to significant year-to-year instability in their relative weights. Although we have always encouraged non-Medicare payers to develop weights applicable to their own patient populations, we have received frequent complaints from providers about the use of the Medicare relative weights in the pediatric population. We believe that eliminating this age split in the MS–DRGs will provide more stable payment for pediatric cases by determining their payment using adult cases that are much higher in total volume. Newborns are unique and require separate MS–DRGs that are not mirrored in the adult population. Therefore, it remains necessary to retain separate MS–DRGs for newborns. All of the low-volume MS–DRGs listed are for newborns. For FY 2017, because we do not have sufficient MedPAR data to set accurate and stable cost relative weights for these low-volume MS–DRGs, we are proposing to compute relative weights for the low-volume MS–DRGs by adjusting their final FY 2016 relative weights by the percentage change in the average weight of the cases in other MS–DRGs. The crosswalk table is shown:

Low-volume MS–DRG	MS–DRG title	Crosswalk to MS–DRG
768	Vaginal Delivery with O.R. Procedure Except Sterilization and/or D&C.	Final FY 2016 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
789	Neonates, Died or Transferred to Another Acute Care Facility.	Final FY 2016 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
790	Extreme Immaturity or Respiratory Distress Syndrome, Neonate.	Final FY 2016 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
791	Prematurity with Major Problems	Final FY 2016 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
792	Prematurity without Major Problems	Final FY 2016 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
793	Full-Term Neonate with Major Problems	Final FY 2016 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
794	Neonate with Other Significant Problems	Final FY 2016 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
795	Normal Newborn	Final FY 2016 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).

We are inviting public comments on this proposal.

H. Proposed Add-On Payments for New Services and Technologies for FY 2017

1. Background

Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies (sometimes collectively referred to in this section as "new technologies") under the IPPS. Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered new if it meets criteria established by the Secretary after notice and opportunity for public comment. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that a new medical service or technology may be considered for new technology add-on payment if, based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate. We note that, beginning with discharges occurring in FY 2008, CMS transitioned from CMS–DRGs to MS–DRGs.

The regulations at 42 CFR 412.87 implement these provisions and specify three criteria for a new medical service or technology to receive the additional payment: (1) The medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. Below we highlight some of the major statutory and regulatory provisions relevant to the new technology add-on payment criteria, as well as other information. For a complete discussion on the new technology add-on payment criteria, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51572 through 51574).

Under the first criterion, as reflected in § 412.87(b)(2), a specific medical service or technology will be considered "new" for purposes of new medical service or technology add-on payments until such time as Medicare data are available to fully reflect the cost of the technology in the MS–DRG weights through recalibration. We note that we do not consider a service or technology to be new if it is substantially similar to one or more existing technologies. That is, even if a technology receives a new FDA approval, it may not necessarily be considered "new" for purposes of new technology add-on payments if it is "substantially similar" to a technology that was approved by FDA and has been on the market for more than 2 to 3 years. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 through 43814), we established criteria for evaluating whether a new technology is substantially similar to an existing technology, specifically: (1) Whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) whether a product is assigned to the same or a different MS–DRG; and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. If a technology meets all three of these criteria, it would be considered substantially similar to an existing technology and would not be considered "new" for purposes of new technology add-on payments. For a detailed discussion of the criteria for substantial similarity, we refer readers to the FY 2006 IPPS final rule (70 FR 47351 through 47352), and the FY 2010 IPPS/LTCH PPS final rule (74 FR 43813 through 43814).

Under the second criterion, § 412.87(b)(3) further provides that, to be eligible for the add-on payment for new medical services or technologies, the MS–DRG prospective payment rate otherwise applicable to the discharge involving the new medical services or technologies must be assessed for adequacy. Under the cost criterion, consistent with the formula specified in section 1886(d)(5)(K)(ii)(I) of the Act, to assess the adequacy of payment for a new technology paid under the applicable MS–DRG prospective payment rate, we evaluate whether the charges for cases involving the new technology exceed certain threshold amounts. Table 10 that was released with the FY 2016 IPPS/LTCH PPS final rule contains the final thresholds that we used to evaluate applications for new medical service and new technology add-on payments for FY 2017. We refer readers to the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Final-Rule-Tables.html* to download and view Table 10.

In the September 7, 2001 final rule that established the new technology add-on payment regulations (66 FR 46917), we discussed the issue of whether the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule at 45 CFR parts 160 and 164 applies to claims information that providers submit with applications for new medical service and new technology add-on payments. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51573) for complete information on this issue.

Under the third criterion, § 412.87(b)(1) of our existing regulations provides that a new technology is an appropriate candidate for an additional payment when it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. For example, a new technology represents a substantial clinical improvement when it reduces mortality, decreases the number of hospitalizations or physician visits, or reduces recovery time compared to the technologies previously available. (We refer readers to the September 7, 2001 final rule for a more detailed discussion of this criterion (66 FR 46902).)

The new medical service or technology add-on payment policy under the IPPS provides additional payments for cases with relatively high costs involving eligible new medical services or technologies while preserving some of the incentives inherent under an average-based prospective payment system. The payment mechanism is based on the cost to hospitals for the new medical service or technology. Under § 412.88, if the costs of the discharge (determined by applying cost-to-charge ratios (CCRs) as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 50 percent of the estimated costs of the new technology or medical service (if the estimated costs for the case including the new technology or medical service exceed Medicare's payment); or (2) 50 percent of the difference between the full DRG payment and the hospital's estimated cost for the case. Unless the discharge qualifies for an outlier payment, the additional Medicare payment is limited to the full MS–DRG payment plus 50 percent of the estimated costs of the new technology or new medical service.

Section 503(d)(2) of Public Law 108–173 provides that there shall be no reduction or adjustment in aggregate payments under the IPPS due to add-on payments for new medical services and technologies. Therefore, in accordance with section 503(d)(2) of Public Law 108–173, add-on payments for new medical services or technologies for FY 2005 and later years have not been subjected to budget neutrality.

In the FY 2009 IPPS final rule (73 FR 48561 through 48563), we modified our regulations at § 412.87 to codify our longstanding practice of how CMS evaluates the eligibility criteria for new medical service or technology add-on payment applications. That is, we first determine whether a medical service or technology meets the newness criterion, and only if so, do we then make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We amended § 412.87(c) to specify that all applicants for new technology add-on payments must have FDA approval or clearance for their new medical service or technology by July 1 of each year prior to the beginning of the fiscal year that the application is being considered.

The Council on Technology and Innovation (CTI) at CMS oversees the agency's cross-cutting priority on coordinating coverage, coding and payment processes for Medicare with respect to new technologies and procedures, including new drug therapies, as well as promoting the exchange of information on new technologies and medical services between CMS and other entities. The CTI, composed of senior CMS staff and clinicians, was established under section 942(a) of Public Law 108–173. The Council is co-chaired by the Director of the Center for Clinical Standards and Quality (CCSQ) and the Director of the Center for Medicare (CM), who is also designated as the CTI's Executive Coordinator.

The specific processes for coverage, coding, and payment are implemented by CM, CCSQ, and the local claims-payment contractors (in the case of local coverage and payment decisions). The CTI supplements, rather than replaces, these processes by working to assure that all of these activities reflect the agency-wide priority to promote high-quality, innovative care. At the same time, the CTI also works to streamline, accelerate, and improve coordination of these processes to ensure that they remain up to date as new issues arise. To achieve its goals, the CTI works to streamline and create a more transparent coding and payment process, improve the quality of medical decisions, and speed patient access to effective new treatments. It is also dedicated to supporting better decisions by patients and doctors in using Medicare-covered services through the promotion of better evidence development, which is critical for improving the quality of care for Medicare beneficiaries.

To improve the understanding of CMS' processes for coverage, coding, and payment and how to access them, the CTI has developed an "Innovator's Guide" to these processes. The intent is to consolidate this information, much of which is already available in a variety of CMS documents and in various places on the CMS Web site, in a user-friendly format. This guide was published in 2010 and is available on the CMS Web site at: *http://www.cms.gov/CouncilonTechInnov/Downloads/InnovatorsGuide5_10_10.pdf.*

As we indicated in the FY 2009 IPPS final rule (73 FR 48554), we invite any product developers or manufacturers of new medical services or technologies to contact the agency early in the process of product development if they have questions or concerns about the evidence that would be needed later in the development process for the agency's coverage decisions for Medicare.

The CTI aims to provide useful information on its activities and initiatives to stakeholders, including Medicare beneficiaries, advocates, medical product manufacturers, providers, and health policy experts. Stakeholders with further questions about Medicare's coverage, coding, and payment processes, or who want further guidance about how they can navigate these processes, can contact the CTI at *CTI@cms.hhs.gov.*

We note that applicants for add-on payments for new medical services or technologies for FY 2018 must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement, along with a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Complete application information, along with final deadlines for submitting a full application, will be posted as it becomes available on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html.* To allow interested parties to identify the new medical services or technologies under review before the publication of the proposed rule for FY 2018, the CMS Web site also will post the tracking forms completed by each applicant.

2. Public Input Before Publication of a Notice of Proposed Rulemaking on Add-On Payments

Section 1886(d)(5)(K)(viii) of the Act, as amended by section 503(b)(2) of Public Law 108–173, provides for a mechanism for public input before publication of a notice of proposed rulemaking regarding whether a medical service or technology represents a substantial clinical improvement or advancement. The process for evaluating new medical service and technology applications requires the Secretary to—

- Provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries;
- Make public and periodically update a list of the services and technologies for which applications for add-on payments are pending;
- Accept comments, recommendations, and data from the public regarding whether a service or technology represents a substantial clinical improvement; and
- Provide, before publication of a proposed rule, for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data regarding whether a new medical service or technology represents a substantial clinical improvement to the clinical staff of CMS.

In order to provide an opportunity for public input regarding add-on payments for new medical services and technologies for FY 2017 prior to publication of the FY 2017 IPPS/LTCH PPS proposed rule, we published a notice in the **Federal Register** on November 30, 2015 (80 FR 74774), and held a town hall meeting at the CMS Headquarters Office in Baltimore, MD, on February 16, 2016. In the announcement notice for the meeting, we stated that the opinions and presentations provided during the meeting would assist us in our evaluations of applications by allowing public discussion of the substantial clinical improvement criterion for each of the FY 2017 new medical service and technology add-on payment applications before the publication of the FY 2017 IPPS/LTCH PPS proposed rule.

Approximately 76 individuals registered to attend the town hall meeting in person, while additional individuals listened over an open telephone line. We also live-streamed the town hall meeting and posted the town hall on the CMS YouTube Web page at: *https://www.youtube.com/watch?v=dn-R5KGQu-M.* We considered each applicant's presentation made at the town hall meeting, as well as written comments submitted on the applications that were received by the due date of February 26, 2016, in our evaluation of the new technology add-on payment applications for FY 2017 in this proposed rule.

As indicated earlier in this section, CMS is required to provide, before publication of a proposed rule, for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data regarding whether a new medical service or technology represents a substantial clinical improvement to the clinical staff of CMS. In recent years, CMS has live-streamed the town hall meeting through the CMS YouTube Web page and later posted the recorded version of the town hall meeting, in addition to maintaining an open telephone line. We are proposing to conduct future town hall meetings entirely via teleconference and Webcast using the same technologies. Under this proposal, we would continue to publish a notice informing the public of the date of the meeting, as well as requirements for the submission of presentations. We also would continue to maintain an open telephone line, with an option for participation in the Webcast. The recording of the town hall meeting would continue to be available on the CMS You Tube Web page or other CMS Web site following the meeting. This recording would include closed captioning of all presentations and comments. In addition to submitting materials for discussion at the town hall meeting, individuals would continue to be able to submit other written comments after the town hall meeting on whether the service or technology represents a substantial clinical improvement. We are inviting public comments on this proposal.

In response to the published notice and the February 16, 2016 New Technology Town Hall meeting, we received written comments regarding the applications for FY 2017 new technology add-on payments. We summarize below a general comment that does not relate to a specific application for FY 2017 new technology add-on payments. We also summarize comments regarding individual applications, or, if applicable, indicate that there were no comments received in section II.H.5. of the preamble of this proposed rule at the end of each discussion of the individual applications.

Comment: One commenter recommended that CMS broaden the criteria applied in making substantial clinical improvement determinations to require, in addition to existing criteria, consideration of whether the new technology or medical service meets one or more of the following additional suggested criteria: (1) Results in a reduction of the length of a hospital stay; (2) improves patient quality of life; (3) creates long-term clinical efficiencies in treatment; (3) addresses patient-centered objectives as defined by the Secretary; or (4) meets such other criteria as the Secretary may specify. The commenter also suggested that an entity that submits an application for new technology add-on payments be entitled to administrative review of an adverse determination made by the Secretary.

Response: We appreciate these recommendations and suggestions and will consider them in future rulemaking.

We note that the commenter also provided comments that were unrelated to the substantial clinical improvement criterion. As stated earlier, the purpose of the new technology town hall meeting is specifically to discuss the substantial clinical improvement criterion in regard to pending new technology add-on payment applications for FY 2017. Therefore, we are not summarizing these additional comments in this proposed rule. However, the commenter is welcome to resubmit its comments in response to proposals presented in this proposed rule.

3. ICD–10–PCS Section "X" Codes for Certain New Medical Services and Technologies

As discussed in the FY 2016 IPPS/LTCH final rule (80 FR 49434), the ICD–10–PCS includes a new section containing the new Section "X" codes, which began being used with discharges occurring on or after October 1, 2015. Decisions regarding changes to ICD–10–PCS Section "X" codes will be handled in the same manner as the decisions for all of the other ICD–10–PCS code changes. That is, proposals to create, delete, or revise Section "X" codes under the ICD–10–PCS structure will be referred to the ICD–10 Coordination and Maintenance Committee. In addition, several of the new medical services and technologies that have been, or may be, approved for new technology add-on payments may now, and in the future, be assigned a Section "X" code within the structure of the ICD–10–PCS. We posted ICD–10–PCS Guidelines on the CMS Web site at: ***http://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-PCS-and-GEMs.html***, including guidelines for ICD–10–PCS "X" codes. We encourage providers to view the material provided on ICD–10–PCS Section "X" codes.

4. Proposed FY 2017 Status of Technologies Approved for FY 2016 Add-On Payments

a. Kcentra™

CSL Behring submitted an application for new technology add-on payments for Kcentra™ for FY 2014. Kcentra™ is a replacement therapy for fresh frozen plasma (FFP) for patients with an acquired coagulation factor deficiency due to warfarin and who are experiencing a severe bleed. Kcentra™ contains the Vitamin K dependent coagulation factors II, VII, IX and X, together known as the prothrombin complex, and antithrombotic proteins C and S. Factor IX is the lead factor for the potency of the preparation. The product is a heat-treated, non-activated, virus filtered and lyophilized plasma protein concentrate made from pooled human plasma. Kcentra™ is available as a lyophilized powder that needs to be reconstituted with sterile water prior to administration via intravenous infusion. The product is dosed based on Factor IX units. Concurrent Vitamin K treatment is recommended to maintain blood clotting factor levels once the effects of Kcentra™ have diminished.

Kcentra™ was approved by the FDA on April 29, 2013. Under the ICD–10 coding system, Kcentra™ is uniquely identified by ICD–10–CM procedure code 30283B1 (Transfusion of nonautologous 4-factor prothrombin complex concentrate into vein, percutaneous approach).

After evaluation of the newness, cost, and substantial clinical improvement criteria for new technology add-on payments for Kcentra™ and consideration of the public comments we received in response to the FY 2014 IPPS/LTCH PPS proposed rule, we approved Kcentra™ for new technology add-on payments for FY 2014 (78 FR 50575 through 50580). In the application, the applicant estimated that the average Medicare beneficiary would require an average dosage of 2500 International Units (IU). Vials contain 500 IU at a cost of $635 per vial. Therefore, cases of Kcentra™ would incur an average cost per case of $3,175 ($635 × 5). Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum add-on payment for a case of Kcentra™ was $1,587.50 for FY 2014. We refer the reader to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50579) for complete details on the new technology add-on payments for Kcentra™.

As stated above, the new technology add-on payment regulations provide that a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD–9–CM code assigned to the new service or technology (§ 412.87(b)(2)). Our practice has been to begin and end new technology add-on payments on the basis of a fiscal year, and we have generally followed a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend the new technology add-on payment for an additional fiscal year. In general, we extend add-on payments for an additional year only if the 3-year anniversary date of the product's entry on the market occurs in the latter half of the fiscal year (70 FR 47362).

With regard to the newness criterion for Kcentra™, we considered the beginning of the newness period to commence when Kcentra™ was approved by the FDA on April 29, 2013. Because the 3-year anniversary date for Kcentra™ will occur in the latter half of FY 2016 (April 29, 2016), in the FY 2016 IPPS/LTCH PPS final rule, we continued new technology add-on payments for this technology for FY 2016 (80 FR 49437). However, for FY 2017, the 3-year anniversary date of the entry of Kcentra™ on the U.S. market (April 29, 2016) will occur prior to the beginning of FY 2017. Therefore, we are proposing to discontinue new technology add-on payments for this technology for FY 2017. We are inviting public comments on this proposal.

b. Argus® II Retinal Prosthesis System

Second Sight Medical Products, Inc. submitted an application for new technology add-on payments for the Argus® II Retinal Prosthesis System (Argus® II System) for FY 2014. The Argus® II System is an active implantable medical device that is intended to provide electrical stimulation of the retina to induce visual perception in patients who are profoundly blind due to retinitis pigmentosa (RP). These patients have bare or no light perception in both eyes. The system employs electrical signals to bypass dead photo-receptor cells and stimulate the overlying neurons according to a real-time video signal that is wirelessly transmitted from an externally worn video camera. The Argus® II implant is intended to be implanted in a single eye, typically the worse-seeing eye. Currently, bilateral implants are not intended for this technology. According to the applicant, the surgical implant procedure takes approximately 4 hours and is performed under general anesthesia.

With regard to the newness criterion, the applicant received a Humanitarian Device Exemption (HDE) approval from the FDA on February 14, 2013. However, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49924 through 49925), we discussed comments we had received informing CMS that the Argus® II System was not available on the U.S. market until December 20, 2013. The applicant explained that, as part of the lengthy approval process, it was required to submit a request to the Federal Communications Commission (FCC) for a waiver of section 15.209(a) of the FCC rules that would allow the applicant to apply for FCC authorization to utilize this specific RF band. The FCC approved the applicant's waiver request on November 30, 2011. After receiving the FCC waiver of the section 15.209(a) rules, the applicant requested and obtained a required Grant of Equipment Authorization to utilize the specific RF band, which the FCC issued on December 20, 2013. Therefore, the applicant stated that the date the Argus® II System first became available for commercial sale in the United States was December 20, 2013. We agreed with the applicant that, due to the delay, the date of newness for the Argus® II System was December 20, 2013, instead of February 14, 2013.

After evaluation of the new technology add-on payment application and consideration of public comments received, we concluded that the Argus® II System met all of the new technology add-on payment policy criteria. Therefore, we approved the Argus® II System for new technology add-on payments in FY 2014 (78 FR 50580 through 50583). Cases involving the Argus® II System that are eligible for new technology add-on payments currently are identified when one of the following ICD–10–PCS procedure codes is reported: 08H005Z (Insertion of epiretinal visual prosthesis into right eye, open approach); or 08H105Z (Insertion of epiretinal visual prosthesis into left eye, open approach). In the application, the applicant provided a breakdown of the costs of the Argus® II System. The total operating cost of the Argus® II System is $144,057.50. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum add-on payment for a case involving the Argus® II System for FY 2014 was $72,028.75.

With regard to the newness criterion for the Argus® II System, we considered the beginning of the newness period to commence when the Argus® II System became available on the U.S. market on December 20, 2013. Because the 3-year anniversary date for the Argus® II System will occur after FY 2016 (December 20, 2016), in the FY 2016 IPPS/LTCH PPS final rule, we continued new technology add-on payments for this technology for FY 2016 (80 FR 49439). However, for FY 2017, the 3-year anniversary date of the entry of the Argus® II System on the U.S. market (December 20, 2016) will occur in the first half of FY 2017. As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry on to the U.S. market occurs in the latter half of the fiscal year. Therefore, we are proposing to discontinue new technology add-on payments for this technology for FY 2017. We are inviting public comments on this proposal.

c. CardioMEMS™ HF (Heart Failure) Monitoring System

CardioMEMS, Inc. submitted an application for new technology add-on payment for FY 2015 for the CardioMEMS™ HF (Heart Failure) Monitoring System, which is an implantable hemodynamic monitoring system comprised of an implantable sensor/monitor placed in the distal pulmonary artery. Pulmonary artery hemodynamic monitoring is used in the management of heart failure. The CardioMEMS™ HF Monitoring System measures multiple pulmonary artery pressure parameters for an ambulatory patient to measure and transmit data via a wireless sensor to a secure Web site.

The CardioMEMS™ HF Monitoring System utilizes radiofrequency (RF) energy to power the sensor and to measure pulmonary artery (PA) pressure and consists of three components: An Implantable Sensor with Delivery Catheter, an External Electronics Unit, and a Pulmonary Artery Pressure Database. The system provides the physician with the patient's PA pressure waveform (including systolic, diastolic, and mean pressures) as well as heart rate. The sensor is permanently implanted in the distal pulmonary artery using transcatheter techniques in the catheterization laboratory where it is calibrated using a Swan-Ganz catheter. PA pressures are transmitted by the patient at home in a supine position on a padded antenna, pushing one button which records an 18-second continuous waveform. The data also can be recorded from the hospital, physician's office or clinic.

The hemodynamic data, including a detailed waveform, are transmitted to a secure Web site that serves as the Pulmonary Artery Pressure Database, so that information regarding PA pressure is available to the physician or nurse at any time via the Internet. Interpretation of trend data allows the clinician to make adjustments to therapy and can be used along with heart failure signs and symptoms to adjust medications.

The applicant received FDA approval on May 28, 2014.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for the CardioMEMS™ HF Monitoring System and consideration of the public comments we received in response to the FY 2015 IPPS/LTCH PPS proposed rule, we approved the CardioMEMS™ HF Monitoring System for new technology add-on payments for FY 2015 (79 FR 49940). Cases involving the CardioMEMS™ HF Monitoring System that are eligible for new technology add-on payments are identified by either ICD–10–PCS procedure code 02HQ30Z (Insertion of pressure sensor monitoring device into right pulmonary artery, percutaneous approach) or ICD–10–PCS procedure code 02HR30Z (Insertion of pressure sensor monitoring device into left pulmonary artery, percutaneous approach). With the new technology add-on payment application, the applicant stated that the total operating cost of the CardioMEMS™ HF Monitoring System is $17,750. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the CardioMEMS™ HF Monitoring System is $8,875.

With regard to the newness criterion for the CardioMEMS™ HF Monitoring System, we considered the beginning of the newness period to commence when the CardioMEMS™ HF Monitoring System was approved by the FDA on May 28, 2014. Because the 3-year anniversary date of the entry of the CardioMEMS™ HF Monitoring System on the U.S. market will occur in the latter half of FY 2017 (May 28, 2017), we are proposing to continue new technology add-on payments for this technology for FY 2017. The maximum payment for a case involving the CardioMEMS™ HF Monitoring System would remain at $8,875 for FY 2017. We are inviting public comments on our proposal.

d. MitraClip® System

Abbott Vascular submitted an application for new technology add-on payments for the MitraClip® System for FY 2015. The MitraClip® System is a transcatheter mitral valve repair system that includes a MitraClip® device implant, a Steerable Guide Catheter, and a Clip Delivery System. It is designed to perform reconstruction of the insufficient mitral valve for high-risk patients who are not candidates for conventional open mitral valve repair surgery.

With regard to the newness criterion, the MitraClip® System received a premarket approval from the FDA on October 24, 2013. The MitraClip® System is indicated "for the percutaneous reduction of significant symptomatic mitral regurgitation (MR >= 3+) due to primary abnormality of the mitral apparatus (degenerative MR) in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation." The MitraClip® System became immediately available on the U.S. market following FDA approval. The MitraClip® System is a Class III device, and has an investigational device exemption (IDE) for the EVEREST study (Endovascular Valve Edge-to-Edge Repair Study)—IDE G030061, and for the COAPT study (Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Health Failure Patients with Functional Mitral Regurgitation)—IDE G120024. Cases involving the MitraClip® System are identified using ICD–10–PCS procedure code 02UG3JZ (Supplement mitral valve with synthetic substitute, percutaneous approach).

On August 7, 2014, CMS issued a National Coverage Decision (NCD) concerning Transcatheter Mitral Valve Repair procedures. We refer readers to the CMS Web site at: *http://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=273* for information related to this NCD.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for the MitraClip® System and consideration of the public comments we received in response to the FY 2015 IPPS/LTCH PPS proposed rule, we approved the MitraClip® System for new technology add-on payments for FY 2015 (79 FR 49946). As discussed in the FY 2015 IPPS/LTCH PPS final rule, this approval is on the basis of using the MitraClip® consistent with the NCD. The average cost of the MitraClip® System is reported as $30,000. Under section 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the MitraClip® System is $15,000 for FY 2015.

With regard to the newness criterion for the MitraClip® System, we considered the beginning of the newness period to commence when the MitraClip® System was approved by the FDA on October 24, 2013. Because the 3-year anniversary date of the entry of the MitraClip® System on the U.S. market (October 24, 2016) will occur after FY 2016, in the FY 2016 IPPS/LTCH PPS final rule, we continued new technology add-on payments for this technology for FY 2016 (80 FR 49442). However, for FY 2017, the 3-year anniversary date of the entry of MitraClip® System on the U.S. market (October 24, 2016) will occur in the first half of FY 2017. As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry on to the U.S. market occurs in the latter half of the fiscal year. Therefore, we are proposing to discontinue new technology add-on payments for this technology for FY 2017. We are inviting public comments on this proposal.

e. Responsive Neurostimulator (RNS®) System

NeuroPace, Inc. submitted an application for new technology add-on payments for FY 2015 for the use of the RNS® System. (We note that the applicant submitted an application for new technology add-on payments for FY 2014, but failed to receive FDA approval prior to the July 1 deadline.) Seizures occur when brain function is disrupted by abnormal electrical activity. Epilepsy is a brain disorder characterized by recurrent, unprovoked seizures. According to the applicant, the RNS® System is the first implantable medical device (developed by NeuroPace, Inc.) for treating persons diagnosed with epilepsy whose partial onset seizures have not been adequately controlled with antiepileptic medications. The applicant further stated that, the RNS® System is the first closed-loop, responsive system to treat partial onset seizures. Responsive electrical stimulation is delivered directly to the seizure focus in the brain when abnormal brain activity is detected. A cranially implanted programmable neurostimulator senses and records brain activity through one or two electrode-containing leads that are placed at the patient's seizure focus/foci. The neurostimulator detects electrographic patterns previously identified by the physician as abnormal, and then provides brief pulses of electrical stimulation through the leads to interrupt those patterns. Stimulation is delivered only when abnormal electrocorticographic activity is detected. The typical patient is treated with a total of 5 minutes of stimulation a day. The RNS® System incorporates remote monitoring, which allows patients to share information with their physicians remotely.

With regard to the newness criterion, the applicant stated that some patients diagnosed with partial onset seizures that cannot be controlled with antiepileptic medications may be candidates for the vagus nerve stimulator (VNS) or for surgical removal of the seizure focus. According to the applicant, these treatments are not appropriate for, or helpful to, all patients. Therefore, the applicant believed that there is an unmet clinical need for additional therapies for partial onset seizures. The applicant further stated that the RNS® System addresses this unmet clinical need by providing a novel treatment option for treating persons diagnosed with medically intractable partial onset seizures. The applicant received FDA premarket approval on November 14, 2013.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for the RNS® System and consideration of the public comments we received in response to the FY 2015 IPPS/LTCH PPS proposed rule, we approved the RNS® System for new technology add-on payments for FY 2015 (79 FR 49950). Cases involving the RNS® System that are eligible for new technology add-on payments are identified using the following ICD–10–PCS procedure code combination: 0NH00NZ (Insertion of neurostimulator generator into skull, open approach) in combination with 00H00MZ (Insertion of neurostimulator lead into brain, open approach). According to the applicant, cases using the RNS® System would incur an anticipated cost per case of $36,950. Under § 412.88(a)(2) of the regulations, we limit new technology add-on payments to the lesser of 50 percent of the average costs of the device or 50 percent of the costs in excess of the MS–DRG payment rate for the case. As a result, the maximum new technology add-on payment for cases involving the RNS® System is $18,475.

With regard to the newness criterion for the RNS® System, we considered the beginning of the newness period to commence when the RNS® System was approved by the FDA on November 14, 2013. Because the 3-year anniversary date of the entry of the RNS® System on the U.S. market (November 14, 2016) will occur after FY 2016, in the FY 2016 IPPS/LTCH PPS final rule, we continued new technology add-on payments for this technology for FY 2016 (80 FR 49443). However, for FY 2017, the 3-year anniversary date of the entry of RNS® System on the U.S. market (November 14, 2016) will occur in the first half of FY 2017. As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry on to the U.S. market occurs in the latter half of the fiscal year. Therefore, we are proposing to discontinue new technology add-on payments for this technology for FY 2017. We are inviting public comments on this proposal.

f. Blinatumomab (BLINCYTO™ Trade Brand)

Amgen, Inc. submitted an application for new technology add-on payments for FY 2016 for Blinatumomab (BLINCYTO™), a bi-specific T-cell engager (BiTE) used for the treatment of Philadelphia chromosome-negative (Ph-) relapsed or refractory (R/R) B-cell precursor acute-lymphoblastic leukemia (ALL), which is a rare aggressive cancer of the blood and bone marrow. Approximately 6,050 individuals are diagnosed with Ph- R/R B-cell precursor ALL in the United States each year, and approximately 2,400 individuals, representing 30 percent of all new cases, are adults. Ph- R/R B-cell precursor ALL occurs when there are malignant transformations of B-cell or T-cell progenitor cells, causing an accumulation of lymphoblasts in the blood, bone marrow, and occasionally throughout the body. As a bi-specific T-cell engager, the BLINCYTO™ technology attaches to a molecule on the surface of the tumorous cell, as well as to a molecule on the surface of normal T-cells, bringing the two into closer proximity and allowing the normal T-cell to destroy the tumorous cell. Specifically, the BLINCYTO™ technology attaches to a cell identified as CD19, which is present on all of the cells of the malignant transformations that cause Ph- R/R B-cell precursor ALL and helps attract the cell into close proximity of the T-cell CD3 with the intent of getting close enough to allow the T-cell to inject toxins that destroy the cancerous cell. According to the applicant, the BLINCYTO™ technology is the first, and the only, bi-specific CD19-directed CD3 T-cell engager single-agent immunotherapy approved by the FDA.

BLINCYTO™ is administered as a continuous IV infusion delivered at a constant flow rate using an infusion pump. A single cycle of treatment consists of 28 days of continuous infusion, and each treatment cycle followed by 2 weeks without treatment prior to administering any further treatments. A course of treatment would consist of two phases. Phase 1 consists of initial inductions or treatments intended to achieve remission followed by additional inductions and treatments to maintain consolidation; or treatments given after remission has been achieved to prolong the duration. During phase 1 of a single treatment course, up to two cycles of BLINCYTO™ are administered, and up to three additional cycles are administered during consolidation. The recommended dosage of BLINCYTO™ administered during the first cycle of treatment is 9 mcg per day for the first 7 days of treatment. The dosage is then increased to 28 mcg per day for 3 weeks until completion. During phase 2 of the treatment course, all subsequent doses are administered as 28 mcg per day throughout the entire duration of the 28-day treatment period.

With regard to the newness criterion, the BLINCYTO™ technology received FDA approval on December 3, 2014, for the treatment of patients diagnosed with Ph- R/R B-cell precursor ALL, and the product gained entry onto the U.S. market on December 17, 2014.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for BLINCYTO™ and consideration of the public comments we received in response to the FY 2016 IPPS/LTCH PPS proposed rule, we approved BLINCYTO™ for new technology add-on payments for FY 2016 (80 FR 49449). Cases involving BLINCYTO™ that are eligible for new technology add-on payments are identified using one of the following ICD–10–PCS procedure codes: XW03351 (Introduction of Blinatumomab antineoplastic immunotherapy into peripheral vein, percutaneous approach, new technology group 1) or XW04351 (Introduction of Blinatumomab antineoplastic immunotherapy into central vein, percutaneous approach, new technology group1).

As discussed in the FY 2016 IPPS/LTCH final rule (80 FR 49449), the applicant recommended that CMS consider and use the cost of the full 28-day inpatient treatment cycle as the expected length of treatment when determining the maximum new technology add-on payment for cases involving the BLINCYTO™ rather than the average cost of lesser number of days used as other variables. For the reasons discussed, we disagreed with the applicant and established the maximum new technology add-on payment amount for a case involving the BLINCYTO™ technology for FY 2016 using the weighted average of the cycle 1 and cycle 2 observed treatment length. Specifically, in the Phase II trial, the most recent data available, 92 patients received cycle 1 for an average length of 21.2 days, and 52 patients received cycle 2 for an average length of 10.2 days. The weighted average of cycle 1 and 2 treatment length is 17 days. We noted that a small number of patients also received 3 to 5 treatment cycles. However, based on the data provided, these cases do not appear to be typical at this point and we excluded them from this calculation. We noted that, if we included all treatment cycles in this calculation, the weighted average number of days of treatment is much lower, 10 days. Using the clinical data provided by the applicant, we stated that we believe that setting the maximum new technology add-on payment amount for a case involving the BLINCYTO™ technology for FY 2016 based on a 17-day length of treatment cycle is representative of historical and current practice. We also stated that, for FY 2017, if new data on length of treatment are available, we would consider any such data in evaluating the maximum new technology add-on payment amount. However, we did not receive any new data from the applicant to evaluate for FY 2017.

In the application, the applicant estimated that the average Medicare beneficiary would require a dosage of 9mcg/day for the first 7 days under the first treatment cycle, followed by a dosage of 28mcg/day for the duration of the treatment cycle, as well as all days included in subsequent cycles. All vials contain 35mcg at a cost of $3,178.57 per vial. The applicant noted that all vials are single-use. Therefore, we determined that cases involving the use of the BLINCYTO™ technology would incur an average cost per case of $54,035.69 (1 vial/day × 17 days × $3,178.57/vial). Under 42 CFR 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the technology or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment amount for a case involving the use of the BLINCYTO™ is $27,017.85 for FY 2016.

With regard to the newness criterion for BLINCYTO™, we considered the beginning of the newness period to commence when the product gained entry onto the U.S. market on December 17, 2014. Because the 3-year anniversary date of the entry of the BLINCYTO™ on the U.S. market will occur after FY 2017 (December 17, 2017), we are proposing to continue new technology add-on payments for this technology for FY 2017. The maximum payment for a case involving BLINCYTO™ would remain at $27,017.85 for FY 2017. We are inviting public comments on this proposal.

g. Lutonix® Drug Coated Balloon PTA Catheter and In.PACT™ Admiral™ Paclitaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter

Two manufacturers, CR Bard Inc. and Medtronic, submitted applications for new technology add-on payments for FY 2016 for LUTONIX® Drug-Coated Balloon (DCB) Percutaneous Transluminal Angioplasty (PTA) Catheter (LUTONIX®) and IN.PACT™ Admiral™ Paclitaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter (IN.PACT™ Admiral™), respectively. Both of these technologies are drug-coated balloon angioplasty treatments for patients diagnosed with peripheral artery disease (PAD). Typical treatments for patients with PAD include angioplasty, stenting, atherectomy and vascular bypass surgery. PAD most commonly occurs in the femoropopliteal segment of the peripheral arteries, is associated with significant levels of morbidity and impairment in quality of life, and requires treatment to reduce symptoms and prevent or treat ischemic events.[2] Treatment options for symptomatic PAD include noninvasive treatment such as medication and life-style modification (for example, exercise programs, diet, and smoking cessation) and invasive options which include endovascular treatment and surgical bypass. The 2013 American College of Cardiology and American Heart Association (ACC/AHA) guidelines for the management of PAD recommend endovascular therapy as the first-line treatment for femoropopliteal artery lesions in patients suffering from claudication (Class I, Level A recommendation).[3]

According to both applicants, LUTONIX® and IN.PACT™ Admiral™ are the first drug coated balloons that can be used for treatment of patients who are diagnosed with PAD. In the FY 2016 IPPS/LTCH final rule, we stated that because cases eligible for the two devices would group to the same MS–DRGs and we believe that these devices are substantially similar to each other (that is, they are intended to treat the same or similar disease in the same or similar patient population and are purposed to achieve the same therapeutic outcome using the same or similar mechanism of action), we evaluated both technologies as one application for new technology add-on payment under the IPPS. The applicants submitted separate cost and clinical data, and we reviewed and discussed each set of data separately. However, we made one determination regarding new technology add-on payments that applied to both devices. We believe that this is consistent with our policy statements in the past regarding substantial similarity. Specifically, we have noted that approval of new technology add-on payments would extend to all technologies that are substantially similar (66 FR 46915), and that we believe that continuing our current practice of extending a new technology add-on payment without a further application from the manufacturer of the competing product or a specific finding on cost and clinical improvement if we make a finding of substantial similarity among two products is the better policy because we avoid—

- Creating manufacturer-specific codes for substantially similar products;
- Requiring different manufacturers of substantially similar products from having to submit separate new technology applications;
- Having to compare the merits of competing technologies on the basis of substantial clinical improvement; and
- Bestowing an advantage to the first applicant representing a particular new technology to receive approval (70 FR 47351).

CR Bard, Inc. received FDA approval for LUTONIX® on October 9, 2014. Commercial sales in the U.S. market began on October 10, 2014. Medtronic received FDA approval for IN.PACT™ Admiral™ on December 30, 2014. Commercial sales in the U.S. market began on January 29, 2015.

In accordance with our policy, we stated in the FY 2016 IPPS\LTCH final rule (80 FR 49463) that we believe it is appropriate to use the earliest market availability date submitted as the beginning of the newness period. Accordingly, for both devices, we stated that the beginning of the newness period will be October 10, 2014.

After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology payments for the LUTONIX® and IN.PACT™ Admiral™ technologies and consideration of the public comments we received in response to the FY 2016 IPPS/LTCH PPS proposed rule, we approved the LUTONIX® and IN.PACT™ Admiral™ technologies for new technology add-on payments for FY 2016 (80 FR 49469). Cases involving the LUTONIX® and IN.PACT™ Admiral™ technologies that are eligible for new technology add-on payments are identified using one of the ICD–10–PCS procedure codes in the following table:

ICD–10–PCS Code	Code description
047K041	Dilation of right femoral artery with drug-eluting intraluminal device using drug-coated balloon, open approach.

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[2] Tepe G, Zeller T, Albrecht T, Heller S, Schwarzwalder U, Beregi JP, Claussen CD, Oldenburg A, Scheller B, Speck U.: Local delivery of paclitaxel to inhibit restenosis during angioplasty of the leg. N Engl J Med 2008; 358: 689–99.

[3] Anderson JL, Halperin JL, Albert NM, Bozkurt B, Brindis RG, Curtis LH, DeMets D, Guyton RA, Hochman JS, Kovacs RJ, Ohman EM, Pressler SJ, Sellke FW, Shen WK.: Management of patients with peripheral artery disease (compilation of 2005 and 2011 ACCF/AHA guideline recommendations): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol 2013; 61:1555–70. Available at: *http://dx.doi.org/10.1016/j.jacc.2013.01.004.*

ICD–10–PCS Code	Code description
047K0D1	Dilation of right femoral artery with intraluminal device using drug-coated balloon, open approach.
047K0Z1	Dilation of right femoral artery using drug-coated balloon, open approach.
047K341	Dilation of right femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach.
047K3D1	Dilation of right femoral artery with intraluminal device using drug-coated balloon, percutaneous approach.
047K3Z1	Dilation of right femoral artery using drug-coated balloon, percutaneous approach.
047K441	Dilation of right femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047K4D1	Dilation of right femoral artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047K4Z1	Dilation of right femoral artery using drug-coated balloon, percutaneous endoscopic approach.
047L041	Dilation of left femoral artery with drug-eluting intraluminal device using drug-coated balloon, open approach.
047L0D1	Dilation of left femoral artery with intraluminal device using drug-coated balloon, open approach.
047L0Z1	Dilation of left femoral artery using drug-coated balloon, open approach.
047L341	Dilation of left femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach.
047L3D1	Dilation of left femoral artery with intraluminal device using drug-coated balloon, percutaneous approach.
047L3Z1	Dilation of left femoral artery using drug-coated balloon, percutaneous approach.
047L441	Dilation of left femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047L4D1	Dilation of left femoral artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047L4Z1	Dilation of left femoral artery using drug-coated balloon, percutaneous endoscopic approach.
047M041	Dilation of right popliteal artery with drug-eluting intraluminal device using drug-coated balloon, open approach.
047M0D1	Dilation of right popliteal artery with intraluminal device using drug-coated balloon, open approach.
047M0Z1	Dilation of right popliteal artery using drug-coated balloon, open approach.
047M341	Dilation of right popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach.
047M3D1	Dilation of right popliteal artery with intraluminal device using drug-coated balloon, percutaneous approach.
047M3Z1	Dilation of right popliteal artery using drug-coated balloon, percutaneous approach.
047M441	Dilation of right popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047M4D1	Dilation of right popliteal artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047M4Z1	Dilation of right popliteal artery using drug-coated balloon, percutaneous endoscopic approach.
047N041	Dilation of left popliteal artery with drug-eluting intraluminal device using drug-coated balloon, open approach.
047N0D1	Dilation of left popliteal artery with intraluminal device using drug-coated balloon, open approach.
047N0Z1	Dilation of left popliteal artery using drug-coated balloon, open approach.
047N341	Dilation of left popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach.
047N3D1	Dilation of left popliteal artery with intraluminal device using drug-coated balloon, percutaneous approach.
047N3Z1	Dilation of left popliteal artery using drug-coated balloon, percutaneous approach.
047N441	Dilation of left popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047N4D1	Dilation of left popliteal artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach.
047N4Z1	Dilation of left popliteal artery using drug-coated balloon, percutaneous endoscopic approach.

As discussed in the FY 2016 IPPS/LTCH final rule (80 FR 49469), each of the applicants submitted operating costs for its DCB. The manufacturer of the LUTONIX® stated that a mean of 1.37 drug-coated balloons was used during the LEVANT 2 clinical trial. The acquisition price for the hospital will be $1,900 per drug-coated balloon, or $2,603 per case (1.37 × $1,900). The applicant projected that approximately 8,875 cases will involve use of the LUTONIX® for FY 2016. The manufacturer for the IN.PACT™ Admiral™ stated that a mean of 1.4 drug-coated balloons was used during the IN.PACT™ Admiral™ DCB arm. The acquisition price for the hospital will be $1,350 per drug-coated balloon, or $1,890 per case (1.4 × $1,350). The applicant projected that approximately 26,000 cases will involve use of the IN.PACT™ Admiral™ for FY 2016.

For FY 2016, we based the new technology add-on payment for cases involving these technologies on the weighted average cost of the two DCBs described by the ICD–10–PCS procedure codes listed above (which are not manufacturer specific). Because ICD–10 codes are not manufacturer specific, we cannot set one new technology add-on payment amount for IN.PACT™ Admiral™ and a different new technology add-on payment amount for LUTONIX®; both technologies will be captured by using the same ICD–10–PCS procedure code. As such, we stated that we believe that the use of a weighted average of the cost of the standard DCBs based on the projected number of cases involving each technology to determine the maximum new technology add-on payment would be most appropriate. To compute the weighted cost average, we summed the total number of projected cases for each of the applicants, which equaled 34,875 cases (26,000 plus 8,875). We then divided the number of projected cases for each of the applicants by the total number of cases, which resulted in the following case-weighted percentages: 25 Percent for the LUTONIX® and 75 percent for the IN.PACT™ Admiral™. We then multiplied the cost per case for the manufacturer specific DCB by the case-weighted percentage (0.25 * $2,603=$662.41 for LUTONIX® and 0.75 * $1,890=$1,409.03 for the IN.PACT™ Admiral™). This resulted in a case-weighted average cost of $2,071.45 for DCBs. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 50 percent of the average cost of the device or 50 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum payment for a case involving the LUTONIX® or IN.PACT™ Admiral™ DCBs is $1,035.72.

With regard to the newness criterion for LUTONIX® and IN.PACT™ Admiral™ technologies, we considered the beginning of the newness period to commence when LUTONIX® gained entry onto the U.S. market on October 10, 2014. Because the 3-year anniversary date of the entry of LUTONIX® on the U.S. market will occur after FY 2017 (October 10, 2017), we are proposing to continue new technology add-on payments for both the LUTONIX® and IN.PACT™ Admiral™ technologies for

FY 2017. The maximum add-on payment for a case involving LUTONIX® and IN.PACT™ Admiral™ would remain at $1,035.72 for FY 2017. We are inviting public comments on this proposal.

5. Proposed FY 2017 Applications for New Technology Add-On Payments

We are reviewing nine applications for new technology add-on payments for FY 2017. In accordance with the regulations under § 412.87(c), applicants for new technology add-on payments must have FDA approval by July 1 of each year prior to the beginning of the fiscal year that the application is being considered. One applicant withdrew its application prior to the issuance of this proposed rule.

a. MAGEC® Spinal Bracing and Distraction System (MAGEC® Spine)

Ellipse Technologies, Inc. submitted an application for new technology add-on payments for FY 2017 for the MAGEC® Spine. According to the applicant, the MAGEC® Spine has been developed for use in the treatment of children diagnosed with severe spinal deformities, such as scoliosis. The system can be used in the treatment of skeletally immature patients less than 10 years of age who have been diagnosed with severe progressive spinal deformities associated with or at risk of Thoracic Insufficiency Syndrome (TIS). The MAGEC® Spine consists of a (spinal growth) rod that can be lengthened through the use of magnets that are controlled by an external remote controller (ERC). The rod(s) can be implanted into children as young as 2 years of age. According to the applicant, use of the MAGEC® Spine has proven to be successfully used in the treatment of patients diagnosed with scoliosis who have not been responsive to other treatments.

The MAGEC® Spine initially received FDA approval for use of the predicate device, which used a Harrington Rod on February 27, 2014. Subsequent FDA approval was granted for use of the modified device, which uses a shorter 70 mm on September 18, 2014. After minor modification of the product, the MAGEC® Spine received its final FDA approvals on March 24, 2015, and May 29, 2015, respectively. Currently, there is no ICD–9–CM or ICD–10–PCS code to uniquely describe procedures involving the MAGEC® Spine.

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 through 43814), we established criteria for evaluating whether a new technology is substantially similar to an existing technology, specifically: (1) Whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) whether a product is assigned to the same or a different MS–DRG; and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. If a technology meets all three of these criteria, it would be considered substantially similar to an existing technology and would not be considered "new" for purposes of new technology add-on payments. For a detailed discussion of the criteria for substantial similarity, we refer readers to the FY 2006 IPPS final rule (70 FR 47351 through 47352), and the FY 2010 IPPS/LTCH PPS final rule (74 FR 43813 through 43814).

With regard to the first criterion, the applicant stated that the MAGEC® Spine's mechanism of action is dependent upon growing rods used for the treatment of patients diagnosed with early onset scoliosis (EOS), and is unique because the technique uses magnetic distraction (lengthening), which does not require the patients to be subjected to the potential and adverse effects of additional surgeries.

The applicant explained that treatment of patients diagnosed with EOS involves the implantation of traditional growth rods (TGRs) followed by surgery every 6 months to distract the rods to accommodate the growing spine until the patient reaches a level of spinal maturity when the spine can then be fused. The average number of distraction surgeries per patient is 12 over the course of 6 years. Once spinal alignment and maturity is reached, the TGRs are surgically and permanently removed. The applicant stated that, while the most recent modification to the MAGEC® Spine's rods accomplish the same goal as the predicate device, Harrington rods, MAGEC® Spine rods achieve the predetermined goal with minimally invasive techniques after implantation, which prevents the patients from being subjected to the potential and adverse effects of numerous lengthening surgeries. The applicant further noted that after the MAGEC® Spine's rod has been implanted, the ERC is placed externally over the patient's spine at the location of the magnet in the MAGEC® Spine's rod. Periodic, noninvasive distraction of the rod is performed to lengthen the spine and to provide adequate bracing during growth. Routine X-ray or ultrasound procedures are used to confirm the position and amount of distraction. The frequency of distraction sessions is customized to the needs of the individual patient by the treating surgeon.

With regard to the first criterion, we are concerned that the MAGEC® Spine uses the same mechanism of action, spinal rod distraction, to achieve the same therapeutic outcome of spinal alignment as other currently available technologies and treatment options for Medicare beneficiaries. Specifically, TGRs are implanted and affixed to the immature spine in order to correct spinal deformities. As a child grows, the TGRs must be distracted to accommodate spinal growth. The common denominator between TGRs and the MAGEC® Spine is that they both are devices (rods) that use the same mechanism of action to perform and achieve spinal distraction, the implantation of rods that are later lengthened. While we acknowledge the applicant noted that the MAGEC® Spine does not require the patient to endure the potential and adverse effects of additional surgeries, this assertion seems to be a component of substantial clinical improvement rather than a basis to distinguish the mechanism of action.

In consideration of the applicant's statements that the mechanism of action of the MAGEC® Spine, which uses growing rods in the treatment of patients diagnosed with EOS, is unique because the technique of using magnetic distraction (lengthening) does not require patients to endure the potential and adverse effects of additional surgeries, we note that there are other technologies and products currently available that achieve spinal growth without the need to subject patients to potential and adverse effects of additional surgeries. For example, the Shilla growth guidance system, which received FDA approval in 2014, uses a non-locking set screw at the proximal and distal portions of the construct's rods. This specific feature is designed to allow the rod to slide through the screw heads as a child's spine grows, while still providing correction of the spinal deformity. The Shilla technique also eliminates the need for scheduled distraction surgeries, as the applicant pointed out are needed with the use of TGRs. Therefore, we believe that the MAGEC® Spine's mechanism of action may be similar to the mechanism of action employed by the Shilla growth guidance system because both technologies achieve the same therapeutic outcome and do not require the patient to endure the potential and adverse effects of additional surgeries.

With regard to the second criterion, cases that may be eligible for treatment involving the MAGEC® Spine map to the following MS–DRGs: 456 (Spinal

Fusion Except Cervical With Spinal Curvature or Malignancy or Infection or Extensive Fusions with MCC); 457 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions with CC); and 458 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions without CC/MCC). All cases involving procedures describing spinal distraction devices, including those that use TGRs and the Shilla growth guidance system, currently map to the same MS–DRGs.

With regard to the third criterion, we believe that the MAGEC® Spine technology involves the treatment of the same or similar type of disease and the same or similar patient population. Although the applicant stated that the MAGEC® Spine was developed for the use in the treatment of children diagnosed with severe spinal deformities, the MAGEC® Spine treats the same patient population as other currently available spinal distraction devices and technologies, including those that use TGRs and the Shilla growth guidance system. Because it appears that the MAGEC® Spine is substantially similar to these other currently available devices used to treat the same or similar types of diseases and the same or similar patient populations, we are concerned that the technology may not be considered "new" for the purposes of new technology add-on payments. We are inviting public comments on whether the MAGEC® Spine meets the newness criterion.

With regard to the cost criterion, the applicant maintained that there is an insufficient number of cases in the Medicare claims data to evaluate because of the small number of potential cases and cases reflecting patients who were actually diagnosed with or who experience early onset scoliosis (EOS) requiring the implantation of growing rods. Specifically, the majority of the Medicare population is 65 years of age and older, while patients who may be eligible for the MAGEC® Spine are typically less than 10 years of age. Therefore, the applicant estimated the number of EOS cases using internal estimates for de novo cases (<10 year of age), as well as cases that could potentially convert to using the MAGEC® Spine without searching the MedPAR data file or any other data source. The applicant estimated that a total of 2,500 EOS cases may be eligible for treatment using the MAGEC® Spine in FY 2016. According to the applicant, 580 cases would map to MS–DRG 456, 870 cases would map to MS–DRG 457, and 1,050 cases would map to MS–DRG 458. The applicant based the distribution of cases on data from its medical advisors, customers, and reimbursement support team.

The applicant used Medicare and non-Medicare data for six providers that used the MAGEC® Spine during CY 2016. This resulted in an average unstandardized case-weighted charge per case of $243,999. The applicant then removed charges related to the predicate technology. Using the Impact File published with the FY 2016 IPPS/LTCH PPS final rule, the applicant standardized the charges and applied an inflation factor of 10 percent. The applicant computed an average CCR of the six hospitals based on the overall hospitals CCRs in the FY 2016 IPPS/LTCH final rule Impact File. The applicant then computed the charges for the device by dividing the costs of the device by the average CCR and added these charges to determine the inflated average standardized case-weighted charge per case. The applicant noted that the cost of the technology was proprietary information. Based on the FY 2016 IPPS/LTCH PPS Table 10 thresholds, the average case-weighted threshold amount was $105,909. The applicant computed an inflated average standardized case-weighted charge per case of $248,037. Because the inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

We have the following concerns regarding the applicant's cost analysis:

- The applicant did not specify how many cases were the basis for the average standardized case-weighted charges per case. Therefore, we cannot determine if the charges per case represent a statistical sample relative to the projected cases eligible for the MAGEC® Spine for the upcoming fiscal year.
- The applicant did not specify how many cases included in the analysis were Medicare and non-Medicare cases. We typically rely on Medicare data and understand the limitations of this patient population in the Medicare data (as the applicant explained above). However, CMS would still like the details regarding the numerical representation of Medicare and non-Medicare cases the applicant used in its analysis.
- The applicant did not explain the methodology it used to remove the charges for the predicate technology, as well as the type of technology that the charges replaced. Therefore, we are unable to validate the accuracy of the applicant's methodology.
- The applicant did not explain the basis of using a 10-percent inflation factor. Specifically, the applicant used cases from CY 2016 and inflated the costs to FY 2017 using a 10-percent inflation factor. However, the 1-year inflation factor in the FY 2016 IPPS/LTCH final rule (80 FR 49784) is 3.7 percent. Therefore, we do not believe that a 10-percent inflation factor is appropriate.

The applicant used the average overall CCR of the six hospitals to convert the costs of the MAGEC® Spine to charges. However, rather than using an average CCR, to increase the precision of determining the charges of the MAGEC® Spine, the applicant could have instead used each hospital's individual CCR or the implantable device CCR of 0.337 as reported in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49429).

We are inviting public comments on whether the MAGEC® Spine meets the cost criterion, particularly with regard to the concerns we have raised.

With regard to substantial clinical improvement, the applicant stated that use of the MAGEC® Spinal Bracing and Distraction System significantly improves clinical outcomes for the pediatric patient population with spinal deformities when compared to technologies and treatment options that employ TGRs by decreasing the number of subsequent surgeries and potential adverse effects following implantation. The applicant provided results from a study[4], which demonstrated that patients receiving treatment using the magnetically controlled growth rods (MCGR) system had 57 fewer surgeries as a whole than those patients receiving treatment options using TGRs. According to the applicant, the results further projected decreased rates of infection and attendant costs because the need for additional distraction (lengthening) surgeries is eliminated. In addition, the applicant stated that 1,500 patients located around the world have been successfully treated with the use of this technology. The applicant indicated that the results from another study[5] cited the following qualitative outcomes: Minimal surgical scarring, decreased psychological distress and improved quality of life, improved pulmonary function tests (PFTs), and capabilities to continuously monitor neurological behaviors because the patient is not exposed to anesthesia during follow-up distractions.

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[4] Akbarnia BA, Cheung K, Noordeen H et al. Traditional rods versus magnetically controlled growing rods in early onset scoliosis: a case-matched two year study. 2013.

[5] Cheng, KMC, Cheung JPY, Damartzis, D, Mak, KC, Wong, WYC, Akbaria, BA, Luk KDK. Magnetically controlled growing rods for sever spinal curvature in young children. A prospective study. Lancet 379 (830) 26 May–1 June 2012, pp. 1967–1974.

We are concerned that the applicant's assertions that the MAGEC® Spine technology leads to significantly better clinical outcomes; specifically, decreased rates of infection, when compared to treatment options that use TGRs has not been shown by the results of the studies provided. The results of the studies provided did not compare rates of infection for patients receiving treatment using the MAGEC® Spine versus patients receiving treatment using TGRs or other spinal growth rods. Also, as previously mentioned, there are other currently available technologies and devices such as the Shilla growth guidance system that also achieve the same therapeutic outcome and do not require the patient to be subjected to the potential and adverse effects of additional surgery. Therefore, we are concerned that the MAGEC® Spine may not represent a substantial clinical improvement over existing technologies. We are inviting public comments on whether the MAGEC® Spine meets the substantial clinical improvement criterion.

We did not receive any written public comments in response to the February 2016 New Technology Town Hall meeting regarding this application for new technology add-on payments.

b. MIRODERM Biologic Wound Matrix (MIRODERM)

Miromatrix Medical, Inc. submitted an application for new technology add-on payments for FY 2017 for MIRODERM. MIRODERM is a non-crosslinked acellular wound matrix that is derived from the porcine liver and is processed and stored in a phosphate buffered aqueous solution. MIRODERM is clinically indicated for the management of wounds, including: Partial and full-thickness wounds, pressure ulcers, venous ulcers, chronic vascular ulcers, diabetic ulcers, trauma wounds, drainage wounds, and surgical wounds. Typical decellularization where tissues are immersed in a decellularization solution is a diffusion-based process, and thereby limits the ability to fully decellularize thick, complex tissues such as the liver. MIRODERM uses a perfusion decellularization process that rapidly removes cellular material while maintaining the native architecture, vasculature and tissue structure. Following decellularization, MIRODERM is isolated from partial thickness liver sections following slight compression of the liver. This allows for the retention of the native liver structure, including the vasculature, within MIRODERM. The applicant noted that the MIRODERM is the only acellular skin substitute product that is derived from the liver.

According to the applicant, MIRODERM is positioned to completely contact the entire surface of the wound bed and extend slightly beyond all wound margins. As required, it is securely anchored to the wound site with a physician's preferred fixation method. An appropriate, primary non-adherent wound dressing is then applied over the MIRODERM matrix. A secondary dressing (multi-layer compression bandage system), total contact cast, or other appropriate dressing that will manage the wound exudate should be applied in order to keep the MIRODERM matrix moist and keep all layers securely in place. Additional applications of MIRODERM are applied as needed until the wound closes.

MIRODERM received FDA approval for its use on January 27, 2015. Currently, there are no ICD–10–PCS procedure codes to uniquely identify the use of MIRODERM. The applicant submitted a request for a unique ICD–10–PCS procedure code that was presented at the March 2016 ICD–10 Coordination and Maintenance Committee meeting. If approved, the procedure codes would become effective on October 1, 2016 (FY 2017). More information on this request can be found on the CMS Web site located at: *http://www.cms.gov/Medicare/Coding/ICD10ProviderDiagnosticCodes/ICD-10-CM-C-and-M-Meeting-Materials.html.*

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered "new" for purposes of new technology add-on payments.

With regard to the first substantial similarity criterion, whether the product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant stated that current wound healing therapies are provided in several different modalities, which include hyperbaric oxygen treatment, negative wound pressure therapy, and treatment with other bioengineered skin substitute products. The applicant noted that other products that have been commonly used for similar procedures are Oasis Wound Matrix, Primatrix Dermal Repair, and Theraskin. The applicant asserted that MIRODERM is different from these other products because it is the only product sourced from porcine liver and undergoes a unique, patented process of perfusion decellularization that rapidly removes cellular material, while maintaining the native architecture, vasculature and tissue structure. The applicant explained that MIRODERM is isolated from partial thickness liver sections following slight compression of the liver, which allows for the retention of the native liver structure, including the vasculature, within MIRODERM. The applicant stated that partial thickness allows for one surface of MIRODERM to retain the native liver capsule (an epithelial basement membrane) and the other opposite surface to be comprised of open liver matrix. The applicant further stated that case studies of the MIRODERM demonstrated accelerated healing, which is likely the result of the unique perfusion decellularization technology that retains a 3-dimensional extracellular matrix that includes the vasculature.

With regard to the first criterion, similar to other current wound matrix treatments, the MIRODERM uses a collagen matrix for tissue repair and regeneration. Therefore, we are concerned that MIRODERM employs the same mechanism of action as other wound matrix treatments. Although the applicant has described how the MIRODERM differs from other wound matrix treatments due to the perfusion decellularization process, and is the first product that is derived from the porcine liver, we believe that the mechanism of action of MIRODERM may be substantially similar or the same as those employed by other wound treatment matrixes. With regard to the second criterion, whether a product is assigned to the same or a different MS–DRG, cases that may be eligible for treatment using MIRODERM map to the same MS–DRGs as other currently approved wound treatment matrixes. With regard to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, MIRODERM is used to treat the same patient population as other currently approved wound treatment matrixes. Because it appears that the MIRODERM may be substantially similar to currently approved wound treatment matrixes, we are concerned that the technology may not be considered "new" for the purposes of new technology add-on payments. We are inviting public comments on whether MIRODERM meets the newness criterion.

With regard to the cost criterion, the applicant conducted the following analysis. The applicant began by researching the 2014 Medicare Inpatient Hospital Standard Analytical File (SAF) file for cases primarily associated with dermal regenerative grafts that may be eligible for treatment using MIRODERM. The applicant searched for claims that reported ICD–9–CM procedure code 86.67 (Dermal regenerative graft) that mapped to one of the following MS–DRGs: 463, 464, and 465 (Wound Debridement and Skin Graft Except Hand for Musculoskeletal System and Connective Tissue Disorders with MCC, with CC, or without CC/MCC, respectively); 573, 574, and 575 (Skin Graft for Skin Ulcer or Cellulitis with MCC, with CC, or without CC/MCC, respectively); 576, 577, and 578 (Skin Graft Except for Skin Ulcer or Cellulitis with MCC, with CC, or without CC/MCC, respectively); 622, 623, and 624 (Skin Grafts and Wound Debridement for Endocrine, Nutritional and Metabolic Diseases with MCC, with CC or without CC/MCC, respectively); and 904 and 905 (Skin Grafts for Injuries with CC/MCC or without CC/MCC, respectively). As a result, the applicant identified 1,130 cases across the MS–DRGs listed, which resulted in an average case-weighted charge per case of $83,059.

Included in the average case-weighted charge per case were charges for other previously used dermal regenerative grafts. According to the applicant, the MIRODERM would replace the need for other dermal regenerative grafts and, therefore, the applicant removed charges related to the use of other currently used dermal regenerative grafts from the average case-weighted charge per case. Specifically, using the January 2016 CMS Part B Drug Pricing File, the applicant first computed an average cost per square centimeter for currently used dermal regenerative grafts (Apligraf $31.207/cm^2, Oasis $10.676/cm^2, Integra DRT $21.585/cm^2, Dermagraft $32.858/cm^2, Integra skin substitute $35.627/cm^2, Primatrix $37.590/cm^2, and Theraskin $38.474/cm^2), which equaled $29.72/cm^2. To determine the average amount of square centimeters of the other dermal regenerative grafts used for each case within the MS–DRG, given the vast complexity and variation in wounds, the applicant used clinical judgment based on experience, observation and typical sizes and depths of wounds that would present on different parts of the body. For an example, wounds on the hand would typically be smaller than those located on the lower extremities. The applicant also assumed that other dermal regenerative grafts would require three applications to close a wound as opposed to treatment using MIRODERM, which requires only two applications. Based on this assumption, the applicant noted that it assumed that the first application required 100 percent of the amount of skin substitute required to treat the original wound area, the second application required 70 percent, and the third application required 40 percent, totaling 210 percent. To compute the total amount of square centimeters used for each case within the MS–DRG, the applicant multiplied this percentage (210 percent) by the amount of square centimeters used for the first application for each case within the MS–DRG. The applicant then multiplied the average cost of the other previously used dermal regenerative grafts ($29.72/cm^2) by the average amount of centimeters used for each case within the MS–DRG to determine the average cost of the other previously used dermal regenerative grafts for each case within the MS–DRG. To convert the costs to charges, the applicant computed an average CCR for each MS–DRG using CCRs from the FY 2014 Standardizing File of the hospitals indicated on each of the claims for each case within the MS–DRG. The applicant then divided the average cost of the other previously used dermal regenerative grafts for each MS–DRG by the average CCR for each MS–DRG to determine the average charges of the other previously used dermal regenerative grafts for each MS–DRG. The applicant also reduced the charges for the number of days of hospitalization by 30 percent because the applicant believed that MIRODERM heals patients faster than the other currently used dermal regenerative grafts, resulting in a reduction in the average lengths of stay. The applicant then deducted the charges related to the other previously used dermal regenerative grafts and the charges for the reduction in the average lengths of stay from the average case-weighted charge per case and then standardized the charges, which resulted in an average standardized case-weighted charge per case of $34,279. The applicant then inflated the average standardized case-weighted charge per case by 7.7 percent, the same inflation factor used by CMS to update the FY 2016 outlier threshold (80 FR 49784).

After inflating the charges it was necessary to add the associated charges for the use of MIRODERM. The applicant conducted a similar calculation to compute the charges for MIRODERM. Specifically, the applicant used clinical judgment based on experience, observation, and typical sizes and depths of wounds that would be present on different parts of the body. The applicant stated that because MIRODERM has shown greater efficacy in wound closure based on their case series, the applicant modeled for only two applications with 50 percent closure of the wound after the first application and full closure of the wound after the second application. Based on this assumption, the applicant noted that it assumed that the first application required 100 percent of the amount of skin substitute required to treat the original wound area and the second application required 50 percent, totaling 150 percent. To compute the total amount of square centimeters used for each MS–DRG, the applicant multiplied this percentage (150 percent) by the amount of square centimeters used for the first application for each MS–DRG. The applicant then multiplied the cost per square centimeter for MIRODERM by the average amount of centimeters used for each case within the MS–DRG to determine the average cost of MIRODERM grafts used for each MS–DRG. Similar to above, to convert the costs to charges, the applicant used the same average CCRs for each MS–DRG and divided the average cost of MIRODERM for each MS–DRG by the average CCR for each MS–DRG to determine the average charges of MIRODERM for each MS–DRG. The applicant then added charges related to the use of MIRODERM to the inflated average standardized charges and determined a final inflated average standardized case-weighted charge per case of $94,009. Using the FY 2016 IPPS Table 10 thresholds, the average case-weighted threshold amount was $67,559 (all calculations above were performed using unrounded numbers). Because the final inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

We are inviting public comments on whether the MIRODERM technology meets the cost criterion.

With regard to substantial clinical improvement, the applicant believed that the technology represents a substantial clinical improvement over existing technologies because patients treated with the MIRODERM for complicated wounds heal quicker and avoid additional surgeries. To demonstrate that the technology meets the substantial clinical improvement criterion, the applicant submitted the results of two actual case studies of a complicated wound from necrotizing fasciitis that was treated with the

MIRODERM. According to the applicant, one case study involved a complicated wound that would typically be treated with a diverting colostomy. The applicant noted that that the patient was discharged with intact anoplasty and good sphincter control after 35 days and four applications for MIRODERM. The applicant further stated that the use of MIRODERM demonstrated rapid healing and likely avoided at least two major debilitating surgeries, as well as the emotional and physical impact of a colostomy for 3 to 6 months. In the second case study, according to the applicant, the attending physician estimated the wound would likely take greater than 90 days to close using traditional wound care matrixes. The applicant stated that after 12 days and two applications of MIRODERM the patient was discharged and after 21 days the wound was sutured closed.

The applicant noted that additional patients have been treated with MIRODERM. According to the applicant, given the recent product launch, the case studies have not been completed, but similar results have been communicated to the applicant.

We are concerned that the clinical data the applicant submitted is from a very small sample with no comparisons to other currently approved wound treatment matrixes. Specifically, the applicant submitted data from only two case studies. Also, the applicant compared the use of MIRODERM to the use of other treatments, such as diverting colostomy. While MIRODERM may represent an improvement in treatment options compared to the other treatment options such as diverting colostomy, we are unable to determine if use of MIRODERM represents a substantial clinical improvement when compared to other wound treatment matrixes of other currently approved treatments. We are inviting public comments on whether MIRODERM meets the substantial clinical improvement criterion.

We did not receive any written public comments in response to the February 2016 New Technology Town Hall meeting regarding this application for new technology add-on payments.

c. Idarucizumab

Boehringer Ingelheim Pharmaceuticals, Inc. submitted an application for new technology add-on payments for FY 2017 for Idarucizumab; a product developed as an antidote to reverse the effects of PRADAXA® (Dabigatran), which is also manufactured by Boehringer Ingelheim Pharmaceuticals, Inc. (We note that the applicant submitted an application for new technology add-on payments for FY 2016, but failed to obtain FDA approval prior to the July 1 deadline.) Dabigatran is an oral direct thrombin inhibitor currently indicated to: (1) Reduce the risk of stroke and systemic embolism in patients who have been diagnosed with nonvalvular atrial fibrillation (NVAF); (2) treat deep venous thrombosis (DVT) and pulmonary embolism (PE) in patients who have been administered a parenteral anticoagulant for 5 to 10 days; and (3) reduce the risk of recurrence of DVT and PE in patients who have been previously diagnosed with NVAF. Currently, unlike the anticoagulant Warfarin, there is no specific way to reverse the anticoagulant effect of Dabigatran in the event of a major bleeding episode.

Idarucizumab is a humanized fragment antigen binding (Fab) molecule, which specifically binds to Dabigatran to deactivate the anticoagulant effect, thereby allowing thrombin to act in blood clot formation. The applicant stated that Idarucizumab represents a new pharmacologic approach to neutralizing the specific anticoagulant effect of Dabigatran in emergency situations. Idarucizumab was approved by the FDA on October 16, 2015. The applicant noted that Idarucizumab is the only FDA-approved therapy available to neutralize the anticoagulant effect of Dabigatran. Before the FDA approval of Idarucizumab, the approach for the management of the anticoagulant effect of Dabigatran prior to an invasive procedure was to withhold administration of Dabigatran, when possible, for a certain duration of time prior to the procedure to allow sufficient time for the patient's kidneys to flush out the medication. The duration of time needed to flush out the medication prior to the surgical procedure is based on the patient's kidney function. According to the applicant, if surgery cannot be delayed to allow the kidneys the necessary time to flush out the traces of Dabigatran, there is an increased risk of bleeding.

Based on the FDA indication for Idarucizumab, the product can be used in the treatment of patients who have been diagnosed with NVAF and administered Dabigatran to reverse life-threatening bleeding events, or who require emergency surgery or medical procedures and rapid reversal of the anticoagulant effects of Dabigatran is necessary and desired. The applicant received a unique ICD–10–PCS procedure code that became effective October 1, 2015. The approved procedure code is XW03331 (Introduction of Idarucizumab, Dabigatran reversal agent into central vein, percutaneous approach, New Technology Group 1). We are inviting public comments on whether Idarucizumab meets the newness criterion.

With regard to the cost criterion, the applicant conducted two analyses. The applicant began by researching claims data in the FY 2014 MedPAR file for cases that may be eligible for Idarucizumab using a combination of ICD–9–CM diagnosis and procedure codes. Specifically, the applicant searched the database for cases reporting anticoagulant therapy diagnosis code E934.2 (Agents primarily affecting blood constituents, anticoagulants) or V58.61 (Long-term (current) use of anticoagulants) in combination with either current standard of care procedure code 99.03 (Other transfusion of whole blood), 99.04 (Transfusion of packed cells), 99.05 (Transfusion of platelets), 99.06 (Transfusion of coagulation factors), 99.07 (Transfusion of other serum), or 39.95 (Hemodialysis), and Dabigatran indication diagnosis code 427.31 (Atrial fibrillation), 453.40 (Acute venous embolism and thrombosis of unspecified deep vessels of lower extremity), 453.41 (Acute venous embolism and thrombosis of deep vessels of proximal lower extremity), 453.42 (Acute venous embolism and thrombosis of deep vessels of distal lower extremity), 453.50 (Chronic venous embolism and thrombosis of unspecified deep vessels of lower extremity), 453.51 (Chronic venous embolism and thrombosis of deep vessels of proximal lower extremity), 453.52 (Chronic venous embolism and thrombosis of deep vessels of distal lower extremity), 415.11 (Iatrogenic pulmonary embolism and infarction), 415.12 (Septic pulmonary embolism), 415.13 (Saddle embolus of pulmonary artery), 415.19 (Other pulmonary embolism and infarction), 416.2 (Chronic pulmonary embolism), V12.51 (Personal history of venous thrombosis and embolism), or V12.55 (Personal history of pulmonary embolism).

To further target potential cases that may be eligible for Idarucizumab, the applicant also excluded specific cases based on Dabigatran contraindications, including all cases representing patients who have been diagnosed with chronic kidney disease (CKD) stage V (diagnosis code 585.5), end-stage renal disease (diagnosis code 585.6), prosthetic heart valves (diagnosis code V43.3), and cases representing patients who have been diagnosed with both CKD stage IV (diagnosis code 585.4) and either DVT or PE (using the same ICD–9–CM diagnosis codes listed above). As a result, the applicant identified 84,224 cases that mapped to 684 MS–DRGs. The applicant standardized the charges and computed an average case-weighted standardized charge per case of $60,089.

The applicant then identified hospital charges potentially associated with the current treatments to reverse anticoagulation, specifically charges associated with pharmacy services, dialysis services, and laboratory services for blood work. Due to limitations associated with the claims data, the applicant was unable to determine the specific drugs used to reverse anticoagulation and if these cases represented patients who required laboratory services for blood work or dialysis services unrelated to the reversal of anticoagulation. Therefore, the applicant subtracted 40 percent of the charges related to these three categories from the standardized charge per case, based on the estimation that the full amount of charges associated with these services would not be incurred by hospitals when Idarucizumab is administered for use in the treatment of patients who have been diagnosed with NVAF and Dabigatran is administered during treatment. The applicant then inflated the standardized charge per case by 7.665 percent, the same inflation factor used by CMS to update the FY 2016 outlier threshold (80 FR 49784) and added charges for Idarucizumab. This resulted in an inflated average case-weighted standardized charge per case of $67,617. Using the FY 2016 IPPS Table 10 thresholds, the average case-weighted threshold amount across all 684 MS–DRGs is $55,586 (all calculations above were performed using unrounded numbers). Because the inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion under this analysis.

Further, the applicant conducted an additional analysis using the same data from the FY 2014 MedPAR file and variables used in the previous analysis. However, instead of using potentially eligible cases that mapped to 100 percent of the 684 MS–DRGs identified, the applicant used potentially eligible cases that mapped to the top 75 percent of the 684 MS–DRGs identified. By applying this limitation, the applicant identified 63,033 cases that mapped to 87 MS–DRGs. The applicant computed an inflated average case-weighted standardized charge per case of $55,872. Using the FY 2016 IPPS Table 10 thresholds, the average case-weighted threshold amount across all 87 MS–DRGs is $63,323 (all calculations above were performed using unrounded numbers). Because the inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology also meets the cost criterion under this analysis. We are inviting public comments regarding the applicant's analyses with regard to the cost criterion.

With regard to substantial clinical improvement, according to the applicant, aside from Idarucizumab, there are no other FDA-approved antidotes to reverse the anticoagulant effects of Dabigatran. Management of the treatment of patients who have been diagnosed with NVAF and administered Dabigatran and experience bleeding may often include supportive care such as Hemodialysis and the use of fresh frozen plasma, blood factor products such as prothrombin complex concentrates (PCC), activated prothrombin complex concentrates, and recombinant factor VIIa or delayed intervention. Protamine sulfate and Vitamin K are typically used to reverse the effects of Heparin and Warfarin, respectively. However, due to the mechanism of action in Dabigatran, the applicant maintained that the use of protamine sulfate and Vitamin K may not be effective to reverse the anticoagulant effect of Dabigatran.

The applicant provided information regarding the management of major bleeding events experienced by patients who were administered Dabigatran and Warfarin during the RE–LY trial.[6] During this study, most major bleeding events were only managed by supportive care. Patients who were administered 150 mg of Dabigatran were transfused with pack red blood cells more often when compared to patients who were administered Warfarin (61.4 percent versus 49.9 percent, respectively). However, patients who were administered Warfarin were transfused with plasma more often when compared to patients who were administered 150 mg of Dabigatran (30.2 percent versus 21.6 percent, respectively). In addition, the use of Vitamin K in the treatment of patients who were administered Warfarin was more frequent when compared to the frequency of use in the treatment of patients who were administered 150 mg of Dabigatran (27.3 percent versus 10.3 percent, respectively). The use of PCCs, recombinant factor VIIa and other coagulation factor replacements in the treatment of patients who were administered both Warfarin and 150 mg of Dabigatran was minimal, and did not significantly differ in frequency when compared among patients assigned to either group. Hemodialysis was used in a single case.

The applicant reported that, currently, it is recommended that the administration of Dabigatran be discontinued 1 to 2 days (CrCl ≥50 ml/min) or 3 to 5 days (CrCl <50 ml/min), if possible, before invasive or surgical procedures because of the increased risk of bleeding.[7] A longer period of discontinuation time should be considered for patients undergoing major surgery, spinal puncture, or placement of a spinal or epidural catheter or port, if complete hemostasis is required. The applicant stated that delaying emergency medical or surgical procedures can cause urgent conditions to become more severe if intervention is not initiated. The applicant further maintained that delaying emergency medical or surgical procedures for an extended period of time can ultimately lead to negative healthcare outcomes and increased healthcare costs. The applicant asserted that rapidly reversing the anticoagulant effect of Dabigatran administered to patients that require an urgent medical procedure or surgery allows the medical procedure or surgery to be performed in a timely manner, which in turn may decrease complications and minimize the need for more costly therapies.

The applicant also provided interim data from an ongoing Phase III trial[8 9] in patients who may have life-threatening bleeding, or require emergency procedures. The applicant noted that published results of the interim data based on 90 patients suggested the following: Reversal of the Dabigatran anticoagulant effect, which was evident immediately after administration; reversal was 100 percent in the first 4 hours and greater than 89 percent of patients achieved complete reversal; hemostasis in 35 patients in Group A was restored at a median of 11.4 hours. Also, the 5 gram dose of Idarucizumab was calculated to reverse the total body load of Dabigatran that was associated with the 99th percentile of the Dabigatran levels measured in the RE–LY trial.

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[6] Healy, et al.: Periprocedural bleeding and thromboembolic events with dabigatran compared with Warfarin: results from the randomized evaluation of long-term anticoagulation therapy (RE–LY) randomized trial, Circulation, 2012; 126:343–348.

[7] Pradaxa® (Dabigatran Etexilate Mesylate) prescribing information. Ridgefield, CT: Boehringer Ingelheim; 2014.

[8] Pollack C, et al. Design and rationale for RE–VERSE AD: A phase 3 study of idarucizumab, a specific reversal agent for dabigatran. Thromb Haemost. 2015 Jul; 114(1):198–205.

[9] Pollack C, et al. Idarucizumab for Dabigatran Reversal. N Engl J Med. 2015 Aug 6; 373(6):511–20.

The applicant provided safety data from three Phase I studies and interim data from the Phase III study. In the Phase I study, 110 healthy male patients enrolled in the study were administered dosages of Idarucizumab that ranged from 20 mg to 8 grams. In this study, 135 patients received placebo. The applicant reported that adverse events were generally mild in intensity and nonspecific. Healthy human volunteers enrolled in the Phase I study were administered Idarucizumab in dosages of 2 and 4 grams, which resulted in immediate and complete reversal of the anticoagulant effect of Dabigatran that was sustained for several hours. In the Phase III study, five thrombotic events occurred. One occurred 2 days after treatment and the remainder occurred 7, 9, 13, and 26 days after treatment. These patients were not receiving antithrombotic therapy when the events occurred, and complications or adverse effects can be attributed to patients' underlying medical conditions. Twenty-one patients (13 in Group A and 8 in Group B) had a serious adverse event. The most frequently reported adverse reactions in greater than or equal to 5 percent of the patients treated with Idarucizumab were hypokalemia, delirium, constipation, pyrexia, and pneumonia. The applicant concluded that the data from these studies demonstrated that Idarucizumab effectively, safely, and potently reverses the anticoagulant effect of Dabigatran. We are inviting public comments on whether Idarucizumab meets the substantial clinical improvement criterion.

We did not receive any written public comments in response to the February 2016 New Technology Town Hall meeting regarding this application for new technology add-on payments.

d. Titan Spine (Titan Spine Endoskeleton® nanoLOCK™ Interbody Device)

Titan Spine submitted an application for new technology add-on payments for the Titan Spine Endoskeleton® nanoLOCK™ Interbody Device (the Titan Spine nanoLOCK™) for FY 2017. The Titan Spine nanoLOCK™ is a nanotechnology-based interbody medical device with a dual acid-etched titanium interbody system used to treat patients diagnosed with degenerative disc disease (DDD). One of the key distinguishing features of the device is the surface manufacturing technique and materials, which produce macro, micro, and nano surface textures. According to the applicant, the combination of surface topographies enables initial implant fixation, mimics an osteoclastic pit for bone growth, and produces the nano-scale features that interface with the integrins on the outside of the cellular membrane. Further, the applicant noted that these features generate better osteogenic and angiogenic responses that enhance bone growth, fusion, and stability. The applicant asserted that the Titan Spine nanoLOCK™'s clinical features also reduce pain, improve recovery time, and produces lower rates of device complications such as debris and inflammation.

On October 27, 2014, the Titan Spine nanoLOCK™ received FDA approval for the use of five lumbar interbody devices and one cervical interbody device: The nanoLOCK™ TA-Sterile Packaged Lumbar ALIF Interbody Fusion Device with nanoLOCK™ surface, available in multiple sizes to accommodate anatomy; the nanoLOCK™ TAS-Sterile Packaged Lumbar ALIF Stand Alone Interbody Fusion Device with nanoLOCK™ surface, available in multiple sizes to accommodate anatomy; the nanoLOCK™ TL-Sterile Packaged Lumbar Lateral Approach Interbody Fusion Device with nanoLOCK™ surface, available in multiple sizes to accommodate anatomy; the nanoLOCK™ TO-Sterile Packaged Lumbar Oblique/PLIF Approach Interbody Fusion Device with nanoLOCK™ surface, available in multiple sizes to accommodate anatomy; the nanoLOCK™ TT-Sterile Packaged Lumbar TLIF Interbody Fusion Device with nanoLOCK™ surface, available in multiple sizes to accommodate anatomy and the nanoLOCK™ TC-Sterile Packaged Cervical Interbody Fusion Device with nanoLOCK™ surface, available in multiple sizes to accommodate anatomy. The applicant received FDA approval on December 14, 2015, for the nanoLOCK™ TCS-Sterile Package Cervical Stand Alone Interbody Fusion Device with nanoLOCK™ surface, available in multiple sizes to accommodate anatomy. Currently, there are no ICD–10–PCS procedure codes that uniquely describe procedures involving use of the Titan Spine nanoLOCK™ surface technology.

We note that cases reporting procedures involving lumbar and cervical interbody devices map to different MS–DRGs. As discussed in the Inpatient New Technology Add-On Payment Final Rule (66 FR 46915), two separate reviews and evaluations of the technologies are necessary in this instance because cases representing patients receiving treatment for diagnoses associated with lumbar procedures that may be eligible for use of the technology under the first indication are not expected to be assigned to the same MS–DRGs as patients receiving treatment for diagnoses associated with cervical procedures using the technology under the second indication. Specifically, cases representing patients who have been diagnosed with lumbar DDD and received treatment that involved implanting a lumbar device map to MS–DRGs 028 (Spinal Procedures with MCC), 029 (Spinal Procedures with CC or Spinal Neurostimulators), 030 (Spinal Procedures without CC/MCC), 453 (Combined Anterior/Posterior Spinal Fusion with MCC), 454 (Combined Anterior/Posterior Spinal Fusion with CC), 455 (Combined Anterior/Posterior Spinal Fusion without CC/MCC), 456 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions with MCC), 457 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusion without MCC), 458 (Spinal Fusion Except Cervical with Spinal Curvature or Malignancy or Infection or Extensive Fusions without CC/MCC), 459 (Spinal Fusion Except Cervical with MCC), and 460 (Spinal Fusion Except Cervical without MCC), while cases representing patients who have been diagnosed with cervical DDD and received treatment that involved implanting a cervical interbody device map to MS–DRGs 471 (Cervical Spinal Fusion with MCC), 472 (Cervical Spinal Fusion with CC), and 473 (Cervical Spinal Fusion without CC/MCC). Procedures involving the lumbar and cervical interbody devices are assigned to separate MS–DRGs. Therefore, the devices categorized as lumbar devices and the devices categorized as cervical devices must distinctively (each category) meet the cost criterion and the substantial clinical improvement criterion in order to be eligible for new technology add-on payments beginning in FY 2017. We discuss application of these criteria following discussion of the newness criterion.

As discussed previously in this section, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered "new" for the purposes of new technology add-on payments. We note that the substantial similarity discussion is applicable to both the lumbar and the cervical devices because all of the devices use the Titan Spine nanLOCK™ technology.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant stated that, for both interbody devices (the lumbar and the cervical interbody device), the Titan Spine nanoLOCK™'s surface stimulates osteogenic cellular response to assist in bone formation during fusion. During the manufacturing process, the surface produces macro, micro, and nano-surface textures. The applicant believed that this unique combination and use of these surface topographies represents a new approach to stimulating osteogenic cellular response. The applicant asserted that the macro-scale textured features are important for initial implant fixation. The micro-scale textured features mimic an osteoclastic pit for supporting bone growth. The nano-scale textured features interface with the integrins on the outside of the cellular membrane, which generates the osteogenic and angiogenic (mRNA) responses necessary to promote healthy bone growth and fusion. The applicant provided the results from *in vitro* studies, using human mesenchymal cells (MSCs), which showed positive effects on bone growth related to cellular signaling achieved by using the device's surface, and osteoblasts exhibited a more differentiated phenotype and increased bone morphogenetic protein (BMP) production using titanium alloy substrates as opposed to poly-ether-ether-ketone (PEEK) substrates. The applicant stated that Titan Spine's proprietary and unique surface technology, the Titan Spine nanoLOCK™ interbody devices, contain optimized nano-surface characteristics, which generate the distinct cellular responses necessary for improved bone growth, fusion, and stability. The applicant further stated that the Titan Spine nanoLOCK™'s surface engages with the strongest portion of the endplate, which enables better resistance to subsidence because a unique dual acid-etched titanium surface promotes earlier bone in-growth. The Titan Spine nanoLOCK™'s surface is created by using a reductive process of the titanium itself. The applicant asserted that use of the Titan Spine nanoLOCK™ significantly reduces the potential for debris generated during impaction when compared to treatments using PEEK-based implants coated with titanium. According to the results of an *in vitro* study[10] provided by the applicant, which compared angiogenic factor production using PEEK-based versus titanium alloy surfaces, osteogenic production levels were greater with the use of rough titanium alloy surfaces than the levels produced using smooth titanium alloy surfaces. The results of an additional study[11] provided by the applicant examined whether inflammatory microenvironment generated by cells as a result of use of titanium aluminum-vanadium (Ti-alloy, TiAlV) surfaces is effected by surface microtexture, and whether it differs from the effects generated by PEEK-based substrates. The applicant noted that the use of microtextured surfaces has demonstrated greater promotion of osteoblast differentiation when compared to use of PEEK-based surfaces.

With regard to the second criterion, whether a product is assigned to the same or a different MS–DRG, cases that may be eligible for treatment involving the Titan Spine nanoLOCK™ map to the same MS–DRGs as other (lumbar and cervical) interbody devices currently available to Medicare beneficiaries and also are used for the treatment of patients who have been diagnosed with DDD (lumbar or cervical).

With regard to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant stated that the Titan Spine nanoLOCK™ can be used in the treatment of patients diagnosed with similar types of diseases, such as DDD, and for a similar patient population receiving treatment involving both lumbar and cervical interbody devices.

In summary, the applicant maintained that the Titan Spine nanoLOCK™ technology has a different mechanism of action when compared to other spinal fusion devices. Therefore, the applicant did not believe that the Titan Spine nanoLOCK™ technology is substantially similar to existing technologies.

After reviewing the applicant's statements regarding nonsubstantial similarity of its technology with other existing technologies, we are still concerned that there are other titanium surfaced devices currently available on the U.S. market. While these devices do not use the Titan Spine nanoLOCK™ technology, their surfaces also are made of titanium. Therefore, we believe that the Titan Spine nanoLOCK™ interbody devices may be substantially similar to currently available titanium interbody devices.

We are seeking public comments on whether the Titan Spine Endoskeleton® nanoLOCK™ Interbody Devices are substantially similar to existing technologies and whether these devices meet the newness criterion.

(1) Titan Spine Endoskeleton® nanoLOCK™ Interbody Device for Lumbar DDD

As previously mentioned, the Titan Spine nanoLOCK™ received FDA approval for the use of five lumbar interbody devices on October 27, 2014. To demonstrate that the Titan Spine nanoLOCK™ for Lumbar DDD technology meets the cost criterion, the applicant researched claims data in the FY 2014 MedPAR file for cases assigned to MS–DRGs 028, 029, 030, 453, 454, and 455 reporting any of the ICD–9–CM procedure codes within the code series 81.xx (Repair and plastic operations on joint structures) or code series 084.6x (Replacement of spinal disk), excluding cases reporting the following ICD–9–CM procedure codes describing cervical fusion: 81.01 (Atlas-axis spinal fusion), 81.02 (Other cervical fusion, anterior technique), 81.03 (Other cervical fusion, posterior technique), 81.31 (Refusion of atlas-axis spine), 81.32 (Refusion of other cervical spine, anterior technique), or 81.33 (Refusion of other cervical spine, posterior technique). As a result, the applicant found that all cases potentially eligible for treatment using the technology mapped to MS–DRGs 456, 457, 458, 459, and 460. However, the applicant focused its analyses on MS–DRGs 028 through 030, 453 through 455, and 456 through 460 because these are the MS–DRGs to which cases treated with interbody fusion devices for degenerative disc disease would most likely be assigned. The applicant applied CMS' relative weight filtering process as described in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49424) to ensure the correct claim types were used and the charge details across the cost centers were appropriate.

According to the applicant, 78.03 percent of the 96,281 cases found in the FY 2014 MedPAR file mapped to MS–DRG 460, while the remaining 21.97 percent of cases mapped to MS–DRGs 028 through 030, 453 through 455, and 456 through 459. This resulted in an average case-weighted charge per case of $127,082. The applicant then removed $15,766 for associated charges for other previously used spinal devices. The applicant determined the associated charges to be removed for other previously used devices based on current Titan Spine sales data for the Titan Spine nanolock™ for Lumbar DDD various sizes. The applicant computed the associated charges by multiplying the weighted sales mix by the average sales price for each product in the Titan Spine nanoLOCK™ for Lumbar DDD product line. After the charges for other previously used technologies were removed, the applicant standardized the charges for all cases using the FY 2014 standardizing file posted on the CMS Web site. The applicant excluded all cases without standardized charges, resulting in a total of 96,281 cases. The applicant then inflated the average standardized case-weighted charges from 2014 to 2016 by applying a 2-year rate of inflation factor of 7.7 percent, which is the same inflation factor used by CMS to update the FY 2016 outlier threshold (80 FR 49784).

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[10] Olivares-Navarrete R, Hyzy S, Gittens R. Titanium Alloys Regulate Osteoblast Production of Angiogenic Factors. The Spine Journal, 2013, ep.13. 1563–1570.

[11] Olivares-Navrrete R, Hyzy s, Slosar P, et al. Implant Materials Generate Different Peri-implant Inflammatory Factors. SPINE. 2015: 40:6:339–404.

To calculate the appropriate charges for the Titan Spine nanoLOCK™ for Lumbar DDD, the applicant used a case-weighted charge because the devices implanted are produced and made available in different sizes. To calculate the case-weighted charge for different lumbar device sizes, the applicant determined the average cost to the hospital per device and divided that amount by the national average CCR for implantable devices (0.337) published in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49429). Based on sales data, the applicant then applied a factor of 1.5 per patient to the case-weighted charge by dividing the total number of products sold in the United States by the total invoices generated; with one invoice being the equivalent to one patient and a single surgery. The applicant then added the device-related charges to the inflated average standardized charge per case, which resulted in an inflated average standardized case-weighted charge per case of $167,197. Using the FY 2016 IPPS Table 10 thresholds, the average case-weighted threshold amount was $112,825 (all calculations above were performed using unrounded numbers). Because the final inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

We are inviting public comments on whether the Titan Spine nanoLOCK™ for Lumbar DDD meets the cost criterion, particularly with regard to the assumptions and methodology used in the applicant's analyses.

(2) Titan Spine Endoskeleton® nanoLOCK™ Interbody Device for Cervical DDD

As previously mentioned, Titan Spine received FDA approval for the use of the nanoLOCK™ TC-Sterile Packaged Cervical Interbody Fusion Device with nanoLOCK™ surface on October 27, 2014, and the nanoLOCK™ TCS-Sterile Package Cervical Interbody Fusion Device with nanoLOCK™ surface on December 14, 2015. To demonstrate that the Titan Spine nanoLOCK™ for Cervical DDD meets the cost criterion, the applicant researched claims data in the FY 2014 MedPAR file for cases assigned to MS–DRGs 028, 029, 030, 453, 454, and 455 reporting any of the following ICD–9–CM cervical fusion procedure codes: 81.01, 81.02, 81.03, 81.32, 81.33. The applicant found that all of the cases mapped to MS–DRGs 471, 472, and 473. However, the applicant focused its analysis on MS–DRGs 028 through 030, 453 through 455, and 471 through 473 because these are the MS–DRGs to which cases treated with the implantation of cervical spinal devices for degenerative disc disease would most likely be assigned. Similar to the sensitivity analysis submitted for the Titan Spine nanoLOCK™ for Lumbar DDD, the applicant applied CMS' relative weight filtering process as described in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49424) to ensure the correct claim types were used and the charge details across the cost centers were appropriate.

According to the applicant, 59.47 percent of the 48,187 cases mapped to MS–DRG 473 and 25.65 percent of the cases mapped to MS–DRG 472, while the remaining 14.88 percent of the cases mapped to MS–DRGs 028 through 030, 453 through 455, and 471. This resulted in an average case-weighted charge per case of $83,841. Using the same methodology described above, the applicant removed $4,423 for associated charges for other previously used technologies from the average case-weighted charge per case using current Titan Spine sales data for cervical device sizes and then standardized the charges. The applicant then inflated the average standardized case-weighted charges from 2014 to 2016 by applying the same 2-year rate of inflation factor used above (7.7 percent). Similar to the methodology described above, the applicant calculated $36,023 for associated device related charges for the Titan Spine nanoLOCK™ for Cervical DDD and added this amount to the inflated average standardized case-weighted charge per case, which resulted in a final inflated average standardized case-weighted charge per case of $114,472. Using the FY 2016 IPPS Table 10 thresholds, the average case-weighted threshold amount was $79,827 (all calculations above were performed using unrounded numbers). Because the final inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

We are inviting public comments on whether the Titan Spine nanoLOCK™ for Cervical DDD meets the cost criterion.

With regard to the substantial clinical improvement criterion for the Titan Spine Endoskeleton® nanoLOCK™ Interbody Device for Lumbar and Cervical DDD, the applicant asserted that the Titan Spine nanoLOCK™ substantially improves the treatment of Medicare beneficiaries who have been diagnosed with and receive treatment for serious spinal pathologies, such as DDD, compared to the currently available technologies and treatment options, especially in terms of improved fusion, decreased pain, greater stability, faster recovery times, and lower rates of interbody device related complications, such as debris and inflammation.

The applicant noted that the cellular process that occurs after implantation of the Titan Spine nanoLOCK™ induces the body to produce and regulate its own bone morphogenetic proteins (BMP), which help stimulate bone growth naturally in the human body. According to the applicant, this result supports new bone growth without requiring use of exogenous BMP. The applicant explained that exogenous rhBMPs trigger a significant cytokine related anti-inflammatory reaction that has resulted in adverse side effects. The applicant stated that the Titan Spine nanoLOCK™'s proprietary surface and use promotes endogenous production of osteogenic growth factors, such as BMP–2, BMP–4, BMP–7, and TGF–β1.2, which produce only the physiologic amounts necessary for bone production without the concomitant cytokine related to anti-inflammatory reaction.

The applicant also stated that the unique surface of the TitanSpine nanoLOCK™ differentiates the technology from existing interbody devices, which use materials such as PEEK-based or ceramic surfaces. The applicant explained that these materials cause stem cells to flatten on the surface of the implant and primarily differentiate into fibroblasts (fiber-producing cells). This result is avoided by using the Titan Spine nanoLOCK™ because the nano-textured surface promotes differentiation of osteoblasts (bone-forming cells), which increases bone production around the implant site and increases the potential for a faster and more robust fusion. The applicant further stated that use of titanium and titanium alloy surfaces with rough microtopography demonstrate greater bone apposition, but use of macrotextured titanium and titanium alloy surfaces, such as the Titan Spine nanoLOCK™, promotes osteoblast differentiation and productions of factors that favor bone formation, whereas PEEK-based surfaces do not.

As previously noted, the applicant provided results from *in vitro* studies, using human MSCs, which showed positive effects on bone growth related to cellular signaling achieved from use of the device's surface, and osteoblasts exhibited a more differentiated phenotype and increased bone morphogenetic protein BMP production using titanium alloy substrates as opposed to PEEK-based substrates. The applicant believed that the Titan Spine nanoLOCK™ substantially improves the treatment of Medicare beneficiaries diagnosed with and receiving treatment for serious spinal pathologies, such as DDD, compared to currently available technologies and treatment options for Medicare beneficiaries, especially in terms of improved fusion, decreased pain, greater stability, faster recovery times, and lower rates of interbody device related complications, such as debris and inflammation.

We are concerned that the results of the *in vitro* studies may not necessarily correlate with the clinical results specified by the applicant. Specifically, because the applicant has only conducted *in vitro* studies without obtaining any clinical data from live subjects during a specific clinical trial, we are unable to substantiate the clinical results that the applicant believed the technology achieved from a clinical standpoint based on the results of the studies provided. As a result, we are concerned that the results of the studies provided by the applicant do not demonstrate that the Titan Spine nanoLOCK™ technologies meet the substantial clinical improvement criterion. We are inviting public comments on whether the Titan Spine nanoLOCK™ technologies meet the substantial clinical improvement criterion.

We did not receive any written public comments in response to the February 2016 New Technology Town Hall meeting regarding this application for new technology add-on payments.

e. Andexanet Alfa

Portola Pharmaceuticals, Inc. (Portola) submitted an application for new technology add-on payments for FY 2017 for use of Andexanet Alfa, an antidote used to treat patients who are receiving treatment with an oral Factor Xa inhibitor who suffer a major bleeding episode and require urgent reversal of direct and indirect Factor Xa anticoagulation. Patients at high risk for thrombosis, including those who have been diagnosed with atrial fibrillation (AF) and venous thrombosis (VTE), typically receive treatment using long-term oral anticoagulation agents, such as Warfarin. Factor Xa inhibitors are included in a new class of anticoagulants. Factor Xa inhibitors are oral anticoagulants used to prevent stroke and systemic embolism in patients who have been diagnosed with AF. These oral anticoagulants are also used to treat patients diagnosed with deep-vein thrombosis (DVT) and its complications, pulmonary embolism (PE), and patients who have undergone knee, hip, or abdominal surgery. Rivarobaxan (Xarelto®), apixaban (Eliqis®), and edoxaban (Savaysa®) also are included in the new class of Factor Xa inhibitors, and are often referred to as "novel oral anticoagulants" (NOACs) or "non-vitamin K antagonist oral anticoagulants." Although these anticoagulants have been commercially available since 2010, there is no FDA-approved therapy used for the urgent reversal of any Factor Xa inhibitor as a result of serious bleeding episodes.

Andexanet Alfa has not received FDA approval at the time of the development of this proposed rule. The applicant anticipates receiving FDA approval for use of the technology in approximately June of 2016. Currently, there are no ICD–10–PCS procedure codes that uniquely identify the use of and administration of Andexanet Alfa. We note that the applicant submitted a request for unique ICD–10–PCS procedure codes that was presented at the March 2016 ICD–10 Coordination and Maintenance Committee meeting. If approved, the procedure codes would become effective on October 1, 2016 (FY 2017). More information on this request can be found on the CMS Web site located at: *http://www.cms.gov/Medicare/Coding/ICD10ProviderDiagnosticCodes/ICD-10-CM-C-and-M-Meeting-Materials.html.*

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered "new" for purposes of new technology add-on payments.

The applicant believed that, if approved, Andexanet Alfa would be the first and only antidote available used to treat patients receiving treatment with an oral Factor Xa inhibitor who suffer a major bleeding episode and require urgent reversal of direct and indirect Factor Xa anticoagulation. Therefore, the applicant asserted that the technology is not substantially similar to any other currently approved and available treatment options for Medicare beneficiaries.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, Andexanet Alfa, if approved, would be the first reversal agent that binds to direct Factor Xa inhibitors with high affinity, sequestering the inhibitors, and consequently rapidly reducing free plasma concentration of Factor Xa inhibitors and neutralizing the inhibitors' anticoagulant effect, which allows for the restoration of normal hemostasis. Andexanet Alfa also binds to and sequesters antithrombin III molecules that are complexed with indirect inhibitor molecules, disrupting the capacity of the antithrombin complex to bind to native Factor Xa inhibitors. According to the applicant, Andexanet Alfa represents a significant therapeutic advance by providing rapid reversal of anticoagulation therapy in the event of a serious bleeding episode. Other reversal agents, such as Kcentra™ and Idarucizumab, do not reverse the effects of Factor Xa inhibitors.

With regard to the second criterion, whether a product is assigned to the same or a different MS–DRG, Andexanet Alfa would be the first FDA approved reversal agent for Factor Xa inhibitors. Therefore, the MS–DRGs do not contain cases representing patients that have been treated with any reversal agents for Factor Xa inhibitors.

With regard to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, Andexanet Alfa, if approved, would be the only reversal agent available for treating patients receiving direct or indirect Factor Xa therapy who experience serious, uncontrolled bleeding events or who require emergency surgery. Therefore, Andexanet Alfa would be the first type of treatment option available to this patient population, As a result, it appears that Andexanet Alfa is not substantially similar to any existing technologies. We are inviting public comments on whether Andexanet Alfa meets the substantial similarity criteria and whether Andexanet Alfa meets the newness criterion.

With regard to the cost criterion, the applicant researched the FY 2014 MedPAR claims data file for cases that may be eligible for treatment using Andexanet Alfa. The applicant used three sets of ICD–9–CM codes to identify these cases: (1) Codes identifying cases of patients who were treated with an anticoagulant and, therefore, are at risk of bleeding; (2) Codes identifying cases of patients with a history of conditions that were treated with Factor Xa inhibitors; and (3) codes identifying cases of patients who experienced bleeding episodes as the reason for the current admission. The applicant included with its application the following table displaying a complete list of ICD–9–CM codes that met its selection criteria:

ICD–9–CM codes applicable	Applicable ICD–9–CM code description
V12.50	Personal history of unspecified circulatory disease.
V12.51	Personal history of venous thrombosis and embolism.
V12.52	Personal history of thrombophlebitis.
V12.54	Personal history of transient ischemic attack (TIA), and cerebral infarction without residual deficits.
V12.55	Personal history of pulmonary embolism.
V12.59	Personal history of other diseases of circulatory system.
V43.64	Hip joint replacement.
V43.65	Knee joint replacement.
V58.43	Aftercare following surgery for injury and trauma.
V58.49	Other specified aftercare following surgery.
V58.73	Aftercare following surgery of the circulatory system, NEC.
V58.75	Aftercare following surgery of the teeth, oral cavity and digestive system, NEC.
V58.61	Long-term (current) use of anticoagulants.
E934.2	Anticoagulants causing adverse effects in therapeutic use.
99.00	Perioperative autologous transfusion of whole blood or blood components.
99.01	Exchange transfusion.
99.02	Transfusion of previously collected autologous blood.
99.03	Other transfusion of whole blood.
99.04	Transfusion of packed cells.
99.05	Transfusion of platelets.
99.06	Transfusion of coagulation factors.
99.07	Transfusion of other serum.

The applicant identified a total of 54,200 cases that mapped to 680 MS–DRGs, resulting in an average case-weighted charge per case of $67,197. The applicant also provided an analysis limited to 80 percent of all cases (47,273 cases), which mapped to the top 147 MS–DRGs. Under this analysis, the average case-weighted charge per case was $64,095. Under each of these two analyses, the applicant also provided sensitivity analyses based on variables representing two areas of uncertainty: (1) Whether to remove 40 percent or 60 percent of blood and blood administration charges; and (2) whether to remove pharmacy charges based on the ceiling price of factor eight inhibitor bypass activity (FEIBA), a branded anti-inhibitor coagulant complex, or on the pharmacy indicator 5 (PI5) in the MedPAR data file, which correlates to cases utilizing generic coagulation factors. Overall, the applicant conducted eight sensitivity analyses, and provided the following rationales:

- The applicant chose to remove 40 percent and 60 percent of blood and blood administration charges because patients who require Andexanet Alfa for Factor Xa reversal may still require blood and blood products to treat other conditions. Therefore, it would be inappropriate to remove all of the charges associated with blood and blood administration because all of the charges cannot be attributed to Factor Xa reversal. The applicant maintained that the amounts of blood and blood products required for treatment vary according to the severity of the bleeding. Therefore, the use of Andexanet Alfa may replace 60 percent of blood and blood product administration charges for cases with less severity of bleeding, but only 40 percent of charges for cases with more severe bleeding.
- The applicant maintained that FEIBA is the highest priced clotting factor used for Factor Xa inhibitor reversal, and it is unlikely that pharmacy charges for Factor Xa reversal would exceed the FEIBA ceiling price of $10,570. Therefore, the applicant capped the charges to be removed at $10,570, which in many cases removed 100 percent of the pharmacy charges. The applicant also considered an alternative scenario in which charges associated with pharmacy indicator 5 (PI5) were removed from the costs of cases that included this indicator in the MedPAR data. On average, charges removed from the costs of cases utilizing generic coagulation factors were much lower than the total pharmacy charges.

The applicant noted that, in all eight scenarios, the average standardized case-weighted charge per case for cases eligible for treatment using Andexanet Alfa would exceed the average case-weighted threshold amounts in Table 10 of the FY 2016 IPPS/LTCH PPS final rule by approximately $3,247 to $7,844, depending on the results determined by using the combination of variables of the two areas of uncertainty and the number of MS–DRGs analyzed.

The applicant's order of operations used for each analysis follows: (1) Removing 60 percent or 40 percent of blood and blood administration charges and up to 100 percent of pharmacy charges for PI5 or FEIBA from the average unstandardized case-weighted charge per case; (2) standardizing the charges per cases using the Impact File published with the FY 2014 IPPS/LTCH PPS final rule. After removing the charges for the prior technology and standardizing charges, the applicant applied an inflation factor of 1.076647, which is the 2-year inflation factor in the FY 2016 IPPS/LTCH final rule (80 FR 49784) to update the charges from FY 2014 to FY 2016. The applicant noted that it did not add charges for Andexanet Alfa and related services. Under each scenario, the applicant stated that the inflated average standardized case-weighted charge per case exceeded the average case-weighted threshold (based on the FY 2016 IPPS Table 10 thresholds). Below we provide a table for all eight scenarios that the applicant indicated demonstrate that the technology meets the cost criterion.

Scenario	Inflated average standardized case-weighted charge per case	Average case-weighted threshold amount
100 Percent of Cases, FEIBA, 60 Percent Removal of Blood and Blood Administration Costs	$60,231	$55,799
100 Percent of Cases, PI5, 60 Percent Removal of Blood and Blood Administration Costs	63,643	55,799
100 Percent of Cases, FEIBA, 40 Percent Removal of Blood and Blood Administration Costs	61,651	55,799
100 Percent of Cases, PI5, 40 Percent Removal of Blood and Blood Administration Costs	64,203	55,799
80 Percent of Cases, FEIBA, 60 Percent Removal of Blood and Blood Administration Costs	57,686	54,413
80 Percent of Cases, PI5, 60 Percent Removal of Blood and Blood Administration Costs	60,994	54,413
80 Percent of Cases, FEIBA, 40 Percent Removal of Blood and Blood Administration Costs	59,096	54,413
80 Percent of Cases, PI5, 40 Percent Removal of Blood and Blood Administration Costs	61,558	54,413

The applicant noted that 25 percent of the total volume of cases map to the following 10 MS–DRGs: MS–DRG 378 (Gastrointestinal Hemorrhage with CC), 7.56 percent of all cases; MS–DRG 812 (Red Blood Cell Disorders without MCC), 3.13 percent of all cases; MS–DRG 377 (Gastrointestinal Hemorrhage with MCC), 2.68 percent of all cases; MS–DRG 470 (Major Joint Replacement or Reattachment of Lower Extremity without MCC), 2.32 percent of all cases); MS–DRG 871 (Septicemia or Severe Sepsis without Mechanical Ventilation >96 hours with MCC), 2.26 percent of all cases; MS–DRG 481 (Hip & Femur Procedures, Except Major Joint with CC), 2.08 percent of all cases; MS–DRG 811 (Red Blood Cell Disorders with MCC), 1.70 percent of all cases; MS–DRG 291 (Heart Failure and Shock with MCC), 1.22 percent of all cases; MS–DRG 379 (Gastro intestinal Hemorrhage without CC/MCC), 1.12 percent of all cases; and MS–DRG 683 (Renal Failure with CC), 1.06 percent of all cases. We are concerned that the applicant did not include sensitivity analyses for this subset of cases.

We are inviting public comments on whether Andexanet Alfa meets the cost criterion, including with regard to the concern we have raised.

With regard to the substantial clinical improvement criterion, the applicant asserted that Andexanet Alfa represents a substantial clinical improvement for the treatment of patients receiving direct or indirect Factor Xa therapy who experience serious, uncontrolled bleeding events or who require emergency surgery because it addresses an unmet medical need for a universal antidote to direct and indirect Factor Xa inhibitors; if approved, would be the only agent shown in prospective clinical trials to rapidly (within 2–5 minutes) and sustainably reverse the anticoagulation activity of Factor Xa inhibitors; is potentially non-thrombogenic, as no serious adverse effects of thrombosis were observed in clinical trials; and could supplant current treatments for bleeding from anti-Factor Xa treatment, which have not been shown to be effective in the treatment of all patients.

With regard to addressing an unmet need for a universal antidote to direct and indirect Factor Xa inhibitors, the applicant asserted that the use of any anticoagulant is associated with an increased risk of bleeding, and bleeding complications can be life-threatening. Bleeding is especially concerning in patients treated with Factor Xa inhibitors because there are currently no antidotes to Factor Xa inhibitors available. The applicant stated that Andexanet Alfa has a unique mechanism of action and represents a new biological approach to the treatment of patients who have been diagnosed with acute severe bleeding who require immediate reversal of the Factor Xa inhibitor therapy. The applicant explained that although Andexanet Alfa is structurally very similar to native Factor Xa inhibitors, it has undergone several modifications that restrict its biological activity to reversing the effects of Factor Xa inhibitors by binding with and sequestering direct or indirect Factor Xa inhibitors, which allows native Factor Xa inhibitors to dictate the normal coagulation and hemostasis process. As a result, the applicant maintained that Andexanet Alfa represents a safe and effective therapy for the management of bleeding in a fragile patient population and a substantial clinical improvement over existing technologies and reversal strategies.

The applicant noted the following: On average, patients with a bleeding complication were hospitalized for 6.3 to 7.4 days; the most common therapies currently used to manage bleeding events in patients undergoing anticoagulant treatment are blood transfusions, most frequently with packed red blood cells or fresh frozen plasma; and Vitamin K therapy was used only in 1 percent of Medicare beneficiaries who were receiving treatment with the indirect Factor Xa inhibitor enoxaparin.

The applicant asserted that laboratory studies have failed to provide consistent evidence of "reversal" of the anticoagulant effect of Factor Xa inhibitors across a range of different PCC products and concentrations. Results of thrombin generation assays have varied depending on the format of the assay. Despite years of experience with low molecular weight heparins and pentasaccharide anticoagulants, neither PCCs nor factor eight inhibitor bypassing activity are recognized as safe and effective reversal agents for these Factor Xa inhibitors. Unlike patients taking Vitamin K antagonists, patients receiving treatment with oral Factor Xa inhibitor drugs have normal levels of clotting factors. Therefore, a strategy based on "repleting" factor levels is of uncertain foundation and could result in supra-normal levels of coagulation factors after rapid metabolism and clearance of the oral anticoagulant.

The applicant provided results from two Phase III studies [12] [13] in which older healthy volunteers pretreated with direct or indirect Factor Xa inhibitors (apixaban, edoxaban, rivaroxaban, and enoxaparin) demonstrated the following: Rapid and sustainable reversal of anticoagulation; reduced Factor Xa inhibitor free plasma levels by at least 80 percent below a calculated no-effect level; and reduced anti-Factor Xa activity to the lowest level of detection within 2 to 5 minutes of infusion. The applicant noted that decreased Factor Xa inhibitor levels have been shown to correspond to decreased bleeding complications, reconstitution of activity of coagulation factors, and correction of coagulation.

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[12] Conners, J.M. Antidote for Factor Xa Anticoagulants. N Engl J Med. 2015 Nov 13.

[13] Siegal DM, Curnutte JT, Connolly SJ, et al. Andexanet Alfa for the Reversal of Factor Xa Inhibitor Activity. N Engl J Med. 2015 Nov 11.

The applicant stated that the results from the two Phase III studies and previous proof-of-concept Phase II dose-finding studies[2] showed that use of Andexanet Alfa can rapidly reverse anticoagulation activity of Factor Xa inhibitors and sustain that reversal. Therefore, the applicant asserted that Andexanet Alfa has the potential to successfully treat patients who only need short-duration reversal of the Factor Xa inhibitor anticoagulant, as well as patients who require longer-duration reversal, such as patients experiencing a severe intracranial hemorrhage or requiring emergency surgery. Furthermore, the applicant noted that its technology's duration of action allows for a gradual return of Factor Xa inhibitor concentrations to placebo control levels within 2 hours following the end of infusion.

With regard to Andexanet Alfa's non-thrombogenic nature, as no serious adverse effects of thrombosis were observed in clinical trials, the applicant provided clinical trial data which revealed participants in Phase II and Phase III trials had no thrombotic events and there were no serious or severe adverse events reported. Results also showed that use of Andexanet Alfa has a much lower risk of thrombosis than typical procoagulants because it lacks the region responsible for inducing coagulation. Furthermore, the applicant asserted that Andexanet Alfa is not associated with the known complications seen with red blood cell transfusions.

The applicant asserted that, while the Phase II and Phase III trials and studies measured physiological hallmarks of reversal of NOACs, it is expected that the availability of a safe and reliable Factor Xa reversal will result in an overall better prognosis for patients—potentially leading to a reduction in length of hospital stay, fewer complications, and decreased mortality associated with unexpected bleeding episodes.

The applicant also stated that use of Andexanet Alfa can supplant currently available treatments used for reversing bleeding from anti-Factor Xa treatments, which have not been shown to be effective in the treatment of all patients. With regard to PCCs, NOACs, and FFP, the applicant stated that there is a lack of clinical evidence available for patients taking Factor Xa inhibitors that experience bleeding events. The applicant noted that the case reports provide a snapshot of emergent treatment of these often medically complex anti-Factor Xa-treated patients with major bleeds. However, the applicant stated that these analyses reveal the inconsistent approach in assessing the degree of anticoagulation in the patient and the variability in treatment strategy. The applicant explained that little or no assessment of efficacy in restoring coagulation in the patients was performed, and the major outcomes measures were bleeding cessation or mortality. The applicant concluded that overall, there is very little evidence for the efficacy suggested in some guidelines, and the evidence is insufficient to draw any conclusions.

We are inviting public comments on whether Andexanet Alfa meets the substantial clinical improvement criterion.

Below is a summary of the written comments we received on the Andexanet Alfa application in response to the February 2016 New Technology Town Hall meeting and our response:

Comment: Two commenters supported the approval of new technology add-on payments for Andexanet Alfa. According to the commenters, Andexanet Alfa is a significant clinical improvement over existing therapies used to reverse major bleeding in patients receiving treatment using Factor Xa inhibitors. One commenter stated that Andexanet Alfa would be the first and only antidote to treat patients receiving an oral Factor Xa inhibitor who have suffered a major bleeding episode and require urgent reversal of Factor Xa anticoagulation. Based on professional experience as a first line clinician charged with stabilizing and treating patients with bleeding events or trauma such as assaults and motor vehicle accidents, the commenter stated that patients on anticoagulation therapy present a difficult scenario and they often have comorbidities, which complicate the effectiveness of medical care and put them at risk for complications. The commenter stated that major bleeding is observed in approximately five percent of patients receiving treatment using Factor Xa inhibitors, but only a small subset of those patients require urgent reversal of anti-Factor Xa activity. The commenter believed that, in spite of oral Factor Xa inhibitor's short half-life (7 to 9 hours) and similar or even lower bleeding rates than with warfarin or low molecular weight heparin, the lack of a targeted antidote that is safe for Factor Xa inhibitors is believed to limit these anticoagulants, which do not have a monitoring requirement, nor any dietary restrictions. The commenter believed that a significant disadvantage of Factor Xa inhibitors is the lack of an effective strategy to rapidly reverse the anticoagulant effects in patients requiring emergency surgery or presenting with an emergent bleed. There is currently no agent indicated or proven to be effective for the treatment of patients with Factor Xa inhibitor related bleeding. The commenter believed that Andexanet Alfa would provide clinicians and their patients the ability to restore homeostasis in critical emergency settings for the broad range of bleeds experienced by patients receiving treatment using Factor Xa inhibitors. The commenter compared Andexanet Alfa to Kcentra™ and FEIBA, and noted that both work upstream in the coagulation cascade and thus cannot overcome the effects of the Factor Xa inhibitors. The commenter further stated that human plasma-derived clotting factors were not designed to reverse Factor Xa inhibitors. The commenter also believed that it is well recognized among clinicians that there is a critical need for a reversal agent for the new oral anticoagulants (NOAC) that will rapidly restore normal coagulation, and stated that Andexanet Alfa represents a significant clinical improvement over existing therapies that should be approved for the new technology add-on payments.

Another commenter also believed that Andexanet Alfa represents a significant clinical improvement over existing therapies. The commenter stated that, in the dire moment that a patient presents a critical care team with a life-threatening bleed, reversing coagulation immediately provides the foundation for stabilizing the patient, which is needed to prevent further morbidity and mortality. The commenter also noted Kcentra™'s and FEIBA's inability to affect Factor Xa inhibitors because they act on upstream coagulation cascade factors. The commenter further believed that Andexanet Alfa's mechanism of action is different from the mechanism of action of existing treatments.

Response: We appreciate the commenters' input. We will take these comments into consideration when deciding whether to approve new technology add-on payments for Andexanet Alfa for FY 2017.

f. Defitelio® (Defibrotide)

Jazz Pharmaceuticals submitted an application for new technology add-on payments for FY 2017 for Defibrotide (Defitelio®), a treatment for patients diagnosed with hepatic veno-occlusive disease (VOD) with evidence of multi-organ dysfunction. VOD is a potentially life-threatening complication resulting from hematopoietic stem cell transplantation (HSCT), with an incidence rate of 8 percent to 15 percent of patients experiencing its effects after HSCT. Diagnoses of VOD range in severity from what has been classically defined as a disease limited to the liver (mild) and reversible, to a severe syndrome associated with multi-organ dysfunction or failure and death. Patients treated with HSCT who develop VOD with evidence of multi-organ dysfunction face an immediate risk of death, with a mortality rate of more than 80 percent when only supportive care is used.

VOD is believed to be the result of endothelial cell damage and hepatocellular injury from high-dose conditioning regimens administered prior to receiving treatment with HSCT. Preclinical data suggest that Defitelio® stabilizes endothelial cells by reducing endothelial cell activation and by protecting endothelial cells from further damage. Defitelio® is administered as a 2-hour intravenous infusion every 6 hours. The recommended dosage is 6.25 mg/kg body weight (25mg/kg/day). Defitelio® should be administered for a minimum of 21 days. If after 21 days the signs and symptoms associated with hepatic VOD are not resolved, the administration of Defitelio® should be continued until clinical resolution.

With regard to the newness criterion, according to the manufacturer, Defitelio® received FDA approval in March 30, 2016 and is expected to be commercially available on the U.S. market on April 6, 2016. At this time, the applicant has not submitted any specific information to establish that the technology was not available on the U.S. market as of the FDA approval date or to describe the reasons for a delay of availability until the first week of April 2016. Therefore, we believe the newness period for Defitelio® would begin on March 30, 2016, the date of FDA approval.

There are currently no ICD–10–PCS codes to uniquely identify the intravenous administration of Defitelio®. The applicant submitted an application for the March 9–10, 2016 meeting of the ICD–10 Coordination and Maintenance Committee for a unique ICD–10–PCS procedure code to identify the use of Defitelio. If approved, the procedure code would become effective on October 1, 2016 (FY 2017). More information on this request can be found on the CMS Web site located at: *http://www.cms.gov/Medicare/Coding/ICD10ProviderDiagnosticCodes/ICD-10-CM-C-and-M-Meeting-Materials.html.*

As discussed earlier, if a technology meets all three of the criteria for substantial similarity, it would be considered substantially similar to an existing technology and would not be considered "new" for purposes of new technology add-on payments.

With regard to the first criterion, whether the product uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant maintained that Defitelio® has a unique mechanism of action that is not shared by any other drug on the market used to treat patients diagnosed with VOD with evidence of multi-organ failure. According to the applicant, there are no FDA-approved treatments for VOD other than supportive care. Anticoagulants such as heparin, antithrombin, and tissue plasminogen factor have been used to treat patients diagnosed with VOD, but there is a lack of conclusive evidence that these treatments are effective and they also present a high risk of bleeding. The applicant maintained that Defitelio® addresses the underlying pathology of VOD with evidence of multi-organ failure and its use is effective as a treatment for this form of the disease. According to the applicant, it is speculated that the mechanism of action of the Defitelio® revolves around the stabilization of endothelial cells because endothelial cell damage is believed to be a major contributing factor to the development of VOD. However, we are concerned that this mechanism of action is not well understood by the manufacturer and we are unable to determine whether Defitelio® is substantially similar to the other drugs on the market without full understanding of its distinct mechanism of action.

With regard to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant maintained that cases potentially eligible for treatment using Defitelio® and representing the target patient population mainly group to two MS–DRGs: MS–DRG 014 (Allogeneic Bone Marrow Transplant) and MS–DRG 016 (Autologous Bone Marrow Transplant with CC/MCC). We believe that these are the same MS–DRGs that identify cases of patients treated with supportive care for VOD with multi-organ failure.

With regard to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant asserted that there are no FDA-approved treatments for VOD other than supportive care, such as dialysis or ventilation. In addition, the applicant stated that poor outcomes have been reported for patients treated with nonapproved pharmacological treatments for VOD. These treatments have largely been discontinued because of the high incidence of hemorrhagic complications, particularly among patients diagnosed with multi-organ failure. According to the applicant, Defitelio® would be the first and only FDA-approved treatment for VOD with evidence of multi-organ failure. However, we are concerned that the applicant did not include in its application data comparing the outcomes of patients treated with Defitelio® to outcomes of patients treated only for supportive care. We are concerned that Defitelio® may not produce outcomes that are significantly different than the outcomes of patients treated with supportive care.

We are inviting public comments on whether Defitelio® is substantially similar to existing technologies and whether it meets the newness criterion.

With regard to the cost criterion, the applicant conducted sensitivity analyses using claims data from 2012 through 2014 and determined the results in aggregate and by year. The applicant researched 100 percent of the 2012 through 2014 Inpatient Standard Analytic Files (SAFs) for cases eligible for Defitelio®. Because an ICD–9–CM code specific to treatment for VOD does not exist, the applicant used an algorithm to identify cases to use in its sensitivity analyses. The most appropriate ICD–9–CM diagnosis codes were identified based on clinical criteria used to diagnose VOD and were used to identify cohorts of patients diagnosed with VOD and VOD with multi-organ dysfunction. The applicant first identified claims with an ICD–9–CM procedure code indicating an HSCT (Group A) within a 30-day window; VOD most commonly occurs after receipt of HSCT. The applicant then looked for cases with ICD–9–CM diagnosis codes related to liver injury (Group B) or clinical evidence of suspected VOD symptoms based on at least two relevant ICD–9 diagnosis codes (Group C). Lastly, the applicant filtered out cases that did not show clinical evidence of multi-organ dysfunction based on at least one relevant ICD–9–CM code (Group D).

The applicant submitted the following table indicating the ICD–9–CM codes used for each category of the algorithm.

Table 12—ICD–9 Codes Used for the Premier VOD Algorithm

Group	Title	ICD–9–CM Code	Description
A	Hematopoietic Stem Cell Transplant (HSCT) (at least one code).	41.00	Bone marrow transplant, not otherwise specified.
		41.01	Autologous bone marrow transplant without purging.
		41.02	Allogeneic bone marrow transplant with purging.
		41.03	Allogeneic bone marrow transplant without purging.
		41.04	Autologous hematopoietic stem cell transplant without purging.
		41.05	Allogeneic hematopoietic stem cell transplant without purging.
		41.06	Cord blood stem cell transplant.
		41.07	Autologous hematopoietic stem cell transplant with purging.
		41.08	Allogeneic hematopoietic stem cell transplant.
		41.09	Autologous bone marrow transplant with purging.
B	Liver Injury (at least one code).	453.xx	Other venous embolism and thrombosis.
		570.xx	Acute and subacute necrosis of liver.
		573.8	Other specified disorders of liver.
		573.9	Unspecified disorder of liver.
		459.89	Other specified disorders of the circulatory system.
		277.4	Disorders of bilirubin excretion.
C	VOD Symptoms (at least two codes).	782.4	Hyperbilirubinemia.
		789.1	Hepatomegaly.
		783.1	Abnormal weight gain.
		789.5	Ascites.
D	Multi-Organ Dysfunction (at least one code).	518.8x	Acute/Chronic Respiratory Failure.
		786.09	Other respiratory abnormalities (respiratory distress, except that associated with trauma/surgery in adults, or with RDS in newborns).
		799.02	Hypoxemia.
		518.81	Acute respiratory failure.
		V46.2	Other dependence on machines, supplemental oxygen.
		96.7x	Other continuous invasive mechanical ventilation.
		93.90, 93.91, 93.93, 93.99	Non-invasive mechanical ventilation.
		584.X	Acute renal failure.
		586.X	Renal failure unspecified.
		593.9	Renal Failure.
		39.27, 39.42, 39.95, 54.98	Dialysis, including hemodialysis, peritoneal dialysis, hemofiltration.

Using the above algorithm, the applicant identified a total of 267 patient cases of VOD with multi-organ dysfunction in the 2012–2014 Inpatient SAFs, with 78 patient cases in 2012, 102 patient cases in 2013, and 87 patient cases in 2014, or an average annual patient case volume of 89. The applicant determined that these cases grouped mainly into two MS–DRGs: 014 and 016. The applicant noted that there were no cases in the data from MS–DRG 017 (Autologous Bone Marrow Transplant without CC/MCC). The applicant further noted that there were no cases from MS–DRG 017 because the ICD–9–CM codes identifying VOD with multi-organ dysfunction include serious medical conditions that are listed on the MCC and CC lists. In total, 38 MS–DRGs were represented in the patient cohort, with 27 percent of cases mapping to MS–DRG 014 and 42 percent of cases mapping to MS–DRG 016. The remaining cases mapped to 1 of the 36 remaining MS–DRGs with fewer than 11 cases.

For results in the aggregate, the applicant calculated an average case-weighted charge per case of $427,440 across 267 cases representing diagnoses of VOD with multi-organ dysfunction from 2012 through 2014. The applicant assumed there would be a reduction in the use of selected drugs as a result of using Defitelio® and removed 50 percent of the estimated charges for heparin, furosemide, and spironolactone. The charges for these drugs were estimated based on pricing taken from the Medispan PriceRx database, whose costs were marked up according to the inverse of CCRs from cost center 073 (Drugs Charged to Patients) obtained from providers' 2012, 2013, and 2014 cost reports. The applicant matched these CCRs with the provider numbers on each claim. The applicant removed an average of $2,631 in charges for these drugs from the overall unstandardized charges for Defitelio®.

The applicant then standardized the charges and calculated an average standardized case-weighted charge per case of $310,651. To update the charge data to the current fiscal year, the applicant inflated the charges based on the charge inflation factor of 1.048116 in the FY 2016 IPPS/LTCH final rule (80 FR 49779). The 1-year inflation factor was applied four times to FY 2012 claims, three times to FY 2013 claims, and twice to FY 2014 claims to inflate all charges to 2016. The applicant computed an inflated average standardized case-weighted charge per case of $356,015. Using the FY 2016 IPPS Table 10 thresholds, the average case-weighted threshold amount was $157,951 (all calculations above were performed using unrounded numbers). Because the inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion. The applicant noted that it did not include charges for Defitelio® in the inflated average standardized case-weighted charge per case because the inflated average standardized case-weighted charge per case exceeded the average case-weighted threshold amount without charges for Defitelio®.

The applicant provided a similar analysis for each individual year of the SAF data rather than combining all the data from all 3 years into one analysis. Under the other three analyses, the applicant noted that the average standardized case-weighted charge per case exceeded the average case-weighted threshold amount (as shown in the table below) without inflating the charges and without adding any charges for Defitelio®. We are inviting public comments on whether Defitelio® meets the cost criterion.

SAF year	Average case-weighted threshold amount	Average standardized case-weighted charge per case
2012	$161,469	$347,910
2013	150,585	326,445
2014	163,434	404,883

With regard to the substantial clinical improvement criterion, the applicant maintained that Defitelio® is an effective treatment for VOD as an early onset cause of mortality following HSCT. According to the applicant, patients treated with Defitelio® have improved survival and efficacy rates compared to patients who were not treated with Defitelio®. In increasing the chances of post-HSCT survival, Defitelio® affords the transplant patient the opportunity for engraftment, which could be a potential cure for the underlying disease that required HSCT.

The applicant supported these assertions with clinical evidence from pivotal trial 2005–01, a Phase III historical control study in which patients with VOD with multi-organ failure were given Defitelio® in doses of 25/mg/kg/day for the recommended minimum treatment duration of 21 days. Patients in the historical control group were selected by an independent medical review committee (MRC) from a pool of 6,867 medical charts of patients receiving HSCT that were hospitalized from January 1995 through November 2007. The trial consisted of 102 patients in the Defitelio® treated group and 32 patients in the historical control group. The trial used the survival rate and rate of Complete Response (CR) at Day+100 as clinical endpoints. The observed survival rate at Day+100 in the Defitelio® treated group was 38.2 percent compared to 25 percent in the historical control group. Moreover, the rate of CR by Day+100 post-HSCT for the Defitelio® treated group was 25.5 percent compared to 12.5 percent in the historical control group. The applicant conducted additional analyses that showed improvements in survival outcomes among subgroups of patients with baseline prognostic factors related to worse outcomes.

According to the applicant, running a controlled, blinded, and randomized trial in a patient population with high mortality rates would be unethical. We are concerned that there are limitations to the historical control group used in pivotal trial 2005–01. We believe that the discrepancy between the size of the treatment group (N=102) and the historical control group (N=32) may skew the trial results in favor of the treatment group. We also are uncertain, given the small sample size and historical data used, whether the historical control group is representative of patients with VOD with multi-organ failure. According to the applicant, patients in the historical control group were hospitalized between January 1995 and November 2007. Because of advancements in medicine within this timeframe, we are concerned that the patients in the historical control group cannot be appropriately compared to patients in the treatment group. Moreover, we believe that it is difficult to attribute improved survival and CR rates only to Defitelio® treatment.

We are inviting public comments on whether Defitelio® meets the substantial clinical improvement criterion.

We did not receive any written public comments in response to the February 2016 New Technology Town Hall meeting regarding this application for new technology add-on payments.

g. EDWARDS INTUITY Elite™ Valve System

Edwards Lifesciences submitted an application for new technology add-on payments for the EDWARDS INTUITY Elite™ Valve System (INTUITY) for FY 2017. The device uses a rapid deployment valve system and serves as a prosthetic aortic valve, which is inserted using surgical aortic valve replacement (AVR). The device replaces the diseased native valve in patients with aortic valve disease, including aortic stenosis. The components of the device are: (1) A bovine pericardial aortic bioprosthetic valve; (2) a balloon expandable stainless steel frame; and (3) a textured sealing cloth. The INTUITY valve shares many basic features with other tissue, bioprosthetic valves. The leaflets are made of bovine pericardium, rather than porcine valve tissue, or purely mechanical elements.

With regard to the newness criterion, the applicant submitted an application to the FDA for pre-market approval of the INTUITY valve and anticipates FDA approval prior to July 1, 2016. The applicant indicated that the device would be available on the market shortly after approval. The applicant submitted a request for a unique ICD–10–PCS code for consideration at the March 2016 ICD–10 Coordination and Maintenance Committee meeting. If approved, the codes will be effective on October 1, 2016 (FY 2017). More information on this request can be found on the CMS Web site located at: *http://www.cms.gov/Medicare/Coding/ICD10ProviderDiagnosticCodes/ICD-10-CM-C-and-M-Meeting-Materials.html.*

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered "new" for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant described three aspects of the valve system that are unique relative to existing devices. First, the valve system has a deployment mechanism that allows for rapid deployment and only requires 3 sutures, as opposed to 12 to 18 sutures used in standard valve replacement procedures. Second, the flexible deployment arm allows improved surgical access and visualization, making the surgery less challenging for the surgeon, which improves the likelihood that the surgeon can use a minimally invasive approach. Third, the assembly of the device only allows the correct valve size to be fitted, which ensures that the valve does not slip or migrate, which prevents paravalvular leaks and patient prosthetic mismatch. The applicant maintained that the INTUITY has a different mechanism of action than other prosthetic aortic valves and, therefore, is not substantially similar to those used in standard aortic valve replacement procedures.

With regard to the second and third criteria, the device is used in the same patient population and would be assigned to the same MS–DRGs as cases involving other prosthetic aortic valves. We also received information about the Perceval aortic valve (LivaNova), which received FDA approval in January 2016 and which appears to be a substantially similar aortic valve. If the INTUITY valve were to receive approval for new technology add-on payments, we would consider whether the INTUITY valve is substantially similar to the device that has already received FDA approval. If we determine that it is substantially similar, we note that the start date for determining the duration of new technology add-on payments would be the date of FDA approval for the Perceval aortic valve.

After reviewing the information provided by the applicant with regard to the substantial similarity criteria discussed above, we have the following concerns. First, it appears that this device uses a similar mechanism of action as standard aortic valves; the differences described in the application, with respect to how the valve is placed and secured, and the number of sutures required, do not readily distinguish the mechanism of action from other aortic valves. Second, the MS–DRGs to which cases using the INTUITY would be assigned, as indicated in the application, are the same MS–DRGs to which cases involving standard aortic valves would be assigned. Third, the device is used to treat the same disease and patient population as standard aortic valves. In light of these concerns, we believe that this device appears to be substantially similar to other valves used in aortic valve replacement. We are inviting public comments on whether the INTUITY meets the newness criterion.

With regard to the cost criterion, the applicant researched the FY 2014 MedPAR claims data file to identify cases of patients who represent potential recipients of treatment using the INTUITY. The applicant identified claims that had an ICD–9–CM diagnosis code of 424.1 (Aortic valve disorder) in combination with an ICD–9–CM procedure code of 35.21 (Replacement of aortic valve with tissue) or 35.22 (Open and other replacement of aortic valve). The applicant also identified cases with or without a coronary artery bypass graft (CABG) using the ICD–9–CM procedure codes in the table below.

ICD–9–CM code	Code description
36.10	Aortocoronary bypass for heart revascularization, not otherwise specified.
36.11	(Aorto)coronary bypass of one coronary artery.
36.12	(Aorto)coronary bypass of two coronary arteries.
36.13	(Aorto)coronary bypass of three coronary arteries.
36.14	(Aorto)coronary bypass of four or more coronary arteries.
36.15	Single internal mammary-coronary artery bypass.
36.16	Double internal mammary-coronary artery bypass.
36.17	Abdominal-coronary artery bypass.

The applicant identified a total of 15,291 cases that mapped to MS–DRGs 216 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC), 217 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with CC), 218 (Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization without CC/MCC), 219 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC), 220 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with CC), and 221 (Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization without CC/MCC). The applicant calculated an average unstandardized charge per case of $178,608 for all cases. The applicant then removed 100 percent of the charges for pacemakers, investigational devices, and other implants that would not be required for patients receiving treatment using the INTUITY.

The applicant standardized the charges and then applied an inflation factor of 1.076647, which is the 2-year inflation factor in the FY 2016 IPPS/LTCH final rule (80 FR 49784), to update the charges from FY 2014 to FY 2016. Because the price of the INTUITY has yet to be determined, the applicant calculated the average expected charge using the same price as charged in the recent IDE trial. Although the applicant submitted data that related to the estimated clinical trial cost of the INTUITY, the applicant noted that the cost of the technology was proprietary information. To add charges for the new technology, the applicant assumed a hospital mark-up of approximately 3.0 percent, based on the current average CCR for implantable devices (0.337) as reported in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49429). Based on the FY 2016 IPPS/LTCH PPS Table 10 thresholds, the average case-weighted threshold amount was $163,173. The applicant computed an inflated average standardized case-weighted charge per case of $185,982, which is $22,809 above the average case-weighted threshold amount. Because the inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

We are concerned that the number of individual cases that were identified and provided by the applicant indicated a total of 26,520 cases that would be eligible for treatment using the INTUITY, but the applicant only included 15,291 cases in the final sensitivity analysis. We would like more information from the applicant regarding how it decided upon which cases to include in the sensitivity analysis, as well as further details about how and on what basis the applicant weighted CABG and non-CABG cases. We are inviting public comments on whether the INTUITY meets the cost criterion, including with regard to the concerns we have raised.

With regard to the substantial clinical improvement criterion, the applicant stated that the device improves clinical outcomes for patients undergoing minimally invasive AVR and full-sternotomy AVR. The applicant also stated that the rapid deployment technology enables reduced operative time, specifically cross-clamp time, thereby reducing the period of myocardial ischemia. The applicant also indicated that the flexible deployment arm increases the likelihood that a minimally invasive approach can be used. In addition, the applicant suggested that the device offers a reduction in operative time for full-sternotomy AVR. The applicant noted that clinical results demonstrated significant patient outcome and utilization improvements, including improved patient satisfaction, faster return to normal activity, decreased post-operative pain, reduced mortality and decreased complications, including need for reoperation due to bleeding, reduced recovery time, and reduced length of stay.

According to the applicant, the valve has been tested clinically in several programs. In the TRITON trial (Kocher et al., 2013[14]), 287 patients with aortic stenosis underwent surgery in 1 of 6 European centers. The first 149 patients received the first generation Model 8300A valve, and the next 138 patients received the second generation Model 8300AB. The average age of the patients was 75.7 years. Early, 30-day mortality was 1.7 percent (5/287), the post-operative valve gradient was low, and 75 percent of the patients improved functionally. A total of four valves were explanted in the final 30 days due to bleeding, and three were explanted later for paravalvular leak, endocarditis, and aortic root aneurysms. Follow-up extended to 3 years (mean 1.8 years).

Implantation of the INTUITY using minimally invasive surgery was compared with conventional aortic valve replacement in the CADENCE–MIS randomized trial (Borger et al., 2015[15]) of 100 patients treated in 1 of 5 centers in Germany (3). Aortic cross-clamp time was reduced from 54.0 to 41.3 minutes ($p<0.0001$), and cardiopulmonary bypass time was reduced from 74.4 to 68.8 minutes ($p=0.21$). Early clinical outcomes were similar: Two deaths in the MIS group versus one death in the conventional surgery group ($p = 0.53$), reoperation in one patient in each group, and no differences in other clinical outcomes. The aortic valve gradient was significantly lower in the MIS group: 8.5 vs. 10.3 mmHg.

The applicant also provided information referring to unpublished data about the preliminary outcomes of the Transform trial; this trial included a study arm that compared MIS surgery with the INTUITY valve to historical comparators that involved MIS surgery with another valve. The applicant indicated that key findings of this trial included reduced procedure times and cross-clamp times, reduced reoperations and 30-day mortality, and reduced length of stay for the INTUITY valve relative to historical comparators that involved another valve. The applicant did not provide any details about these outcomes, stating that the data would be submitted for publication after FDA review.

After reviewing the information provided by the applicant, we have the following concerns. We are concerned that the INTUITY does not have sufficient advantages over other alternative surgically implanted valve systems to constitute a substantial clinical improvement. While the studies included with the application demonstrate reduced aortic cross-clamp time, conventional aortic valve replacement was used in the comparison group; therefore, it is unclear whether the reduced aortic cross-clamp time is associated with the INTUITY valve or with MIS surgery in general. We understand that this issue is currently being studied in the Transform trial, which is in progress. We also note that, there have been no conducted trials of the INTUITY valve, implanted using minimally invasive surgery, versus traditional transcatheter aortic valve replacement (TAVR) procedures, which we believe would be the most relevant comparison. We also do not believe that the applicant provided evidence to support its assertion that the use of the INTUITY valve increase the likelihood of MIS surgery being performed. We are inviting public comments on whether the INTUITY valve meets the substantial clinical improvement criterion.

Below is a summary of the written comments we received on the INTUITY valve in response to the February 2016 New Technology Town Hall meeting and our response.

Comment: One commenter stated that the Perceval bioprothesis is substantially similar to the INTUITY valve, in that they both map to the same MS–DRGs 219, 220, and 221; they utilize the same ICD–10 code 02RF8Z (Replacement of aortic valve with zooplastic tissue, open approach); they are intended to treat the same or similar disease and patient population; they are intended to achieve the same therapeutic outcome; and they are both considered to be sutureless/rapid deployment aortic heart valves used for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic valves. The commenter cited several meta-analyses that include both the Perceval and INTUITY valves and consider them clinically equivalent technologies. The commenter also cited excerpts from articles as well as a description of the ongoing Perceval IDE study to provide support for the substantial clinical improvement of sutureless/rapid deployment heart valves. The applicant requested that Perceval and INTUITY valves be considered in the same category for the new technology add-on payment.

Response: We appreciate the commenter's input. We welcome additional input from the public and will take these comments into consideration when deciding whether to approve new technology add-on payments for the INTUITY valve for FY 2017.

h. GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE)

W.L. Gore and Associates, Inc. submitted an application for new technology add-on payments for the GORE® EXCLUDER® Iliac Branch Endoprosthesis (GORE IBE device) for FY 2017. The device consists of two components: The Iliac Branch Component (IBC) and the Internal Iliac Component (IIC). The applicant indicated that each endoprosthesis is pre-mounted on a customized delivery and deployment system allowing for controlled endovascular delivery via bilateral femoral access. According to the applicant, the device is designed to be used in conjunction with the GORE® EXCLUDER® AAA Endoprosthesis for the treatment of patients requiring repair of common iliac or aortoiliac aneurysms. When deployed, the GORE IBE device excludes the common iliac aneurysm from systemic blood flow, while preserving blood flow in the external and internal iliac arteries.

With regard to the newness criterion, the applicant submitted an application to the FDA for pre-market approval of the GORE IBE device, but has not yet received FDA approval. The applicant submitted a request for a unique ICD–10–PCS code that was presented at the March 2016 ICD–10 Coordination and Maintenance Committee meeting. If approved, the code will be effective on October 1, 2016 (FY 2017). More information on this request can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10ProviderDiagnosticCodes/ICD-10-CM-C-and-M-Meeting-Materials.html.*

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered "new" for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant indicated that the GORE IBE device is based on the same design principles as other endovascular repair devices, and its use differs because of the specific target site for implantation. Consequently, it has a different shape and method of delivery from other endovascular devices. The GORE IBE device is similar to the GORE® EXCLUDER® AAA Endoprosthesis, primarily differing in device dimensions to fit within the iliac artery anatomy. With regard to the first criterion, we are concerned that the GORE IBE device has a similar mechanism of action to other stenting grafts used to treat patients with abdominal aortic aneurysms (AAAs) because it repairs the abdominal aortoiliac aneurysm from the inside and is inserted in a similar manner to other abdominal aortoiliac endovascular aneurysm repair devices.

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[14] Kocher AA, Laufer G, Haverich A, et al. One-year outcomes of the surgical treatment of aortic stenosis with a next generation surgical aortic valve (TRITON) trial: A prospective multicenter study of rapid-deployment aortic valve replacement with the EDWARDS INTUITY valve system. J Thorac Cardiovasc Surg. 2013; 145:110–116.

[15] Borger MA, Moustafine V, Conradi L, et al. A randomized multicenter trial of minimally invasive rapid deployment versus conventional full sternotomy aortic valve replacement. Ann Thorac Surg 2015; 99:17–25.

With regard to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant indicated that cases using the GORE IBE device would map to the same MS–DRGs as cases involving other stent-grafts used to treat patients with AAAs. Specifically, similar to cases involving other stent-grafts used to treat AAAs, cases involving the GORE IBE device would be assigned to MS–DRG 268 (Aortic and Heart Assist Procedures except Pulsation Balloon with MCC) and MS–DRG 269 (Aortic and Heart Assist Procedures except Pulsation Balloon without MCC).

With regard to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant indicated that the GORE IBE device is intended to be used in the treatment of patients requiring repair of common iliac or aortoiliac aneurysms. The applicant stated that this device, if approved, would be the first purpose-built endovascular device for patients whose conditions (common iliac or aortoiliac aneurysm) put them at risk for negative clinical outcomes due to limitations of current treatment methods, which may not preserve internal iliac artery perfusion. The applicant described current repair options for these patients as: (a) Intentional occlusion and coverage of the internal iliac artery; (b) undergoing a more extensive surgical operation to place a bypass graft; or (c) use of combinations of devices in a nonindicated, variable, and inconsistent manner. With regard to the third criterion, we are concerned that this device appears to treat a similar type of disease to existing stent grafts.

Based on the statements above, the applicant maintained that the GORE IBE device is not substantially similar to other stent-grafts used to treat patients with AAAs. We are inviting public comments on whether Gore IBE device is substantially similar to existing technologies and whether the technology meets the newness criterion.

With regard to the cost criterion, the applicant researched the FY 2014 MedPAR claims data to identify patients who may be eligible for treatment using the GORE IBE device. The applicant noted that cases eligible for the GORE IBE device would map to MS–DRGs 268 (Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC) and 269 (Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC). The applicant provided two analyses. The first analysis searched for cases that may be potentially eligible for the GORE IBE device by identifying cases with endovascular aneurysm repair (EVAR) with iliac diagnoses. To identify these cases, the applicant searched for cases that had an ICD–9–CM primary procedure code of 39.71 (Endovascular implantation of other graft in abdominal aorta) in combination with a primary diagnosis code of 441.4 (Abdominal aneurysm without mention of rupture) or 441.02 (Dissection of aorta, abdominal). The applicant excluded cases with a diagnosis code of 441.3 (Abdominal aneurysm, ruptured), and cases with atherosclerosis of the lower extremities (ICD–9–CM diagnosis code 440.20 through 440.28). The applicant then identified a subset of cases (1,615 cases) with significant iliac involvement (which indicated use of the prior technology as well as disease extent where the new technology could be used) by searching for cases with a secondary ICD–9–CM diagnosis code of 442.2 (Aneurysm of iliac artery) or 443.22 (Dissection of iliac artery). This subset of cases was used in the analysis with 205 cases that mapped to MS–DRG 268 and 1,410 cases that mapped to MS–DRG 269. As discussed below, the remaining cases (11,926 cases) were used to help evaluate and compare subsequent offset charge calculations (base EVAR cases).

Using the 1,615 cases, the applicant calculated an average unstandardized case-weighted charge per case of $121,527. Charges for the prior technology (implants), which would be offset by the new technology were established by subtracting the average implant charge in the 1,615 cases from the average implant charge in the base EVAR sample. The excess implant charge represents current implant charges being used in EVAR cases with iliac involvement, and was subtracted from the average unstandardized case-weighted charge per case.

The applicant compared the average unstandardized O.R. and radiology charges associated with the new technology from the clinical trial data with the unstandardized O.R. and radiology charges associated with the prior technology from the MedPAR data and noted that O.R. and radiology charges for resources related to the new technology and the prior technology were similar. However, with regard to charges in the intensive care unit (ICU), there was a reduction of 56 percent in ICU associated charges for the new technology. Therefore, the applicant offset the ICU associated charge by 56 percent and deducted this amount from the average unstandardized case-weighted charge per case. The applicant then standardized the charges, but noted that it did not inflate the charges. The applicant added charges for the GORE IBE device by converting the costs of the device to charges using the average CCR for implantable devices (0.337) as reported in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49429). The applicant noted that the cost of the technology was proprietary information. Based on the FY 2016 IPPS/LTCH PPS Table 10 thresholds, the average case-weighted threshold amount was $109,241. The applicant computed an average standardized case-weighted charge per case of $124,129. Because the average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

The second analysis was similar to the first analysis, but searched the MedPAR claims data file for cases with an EVAR with an iliac diagnosis and procedure instead of cases with EVAR and only an iliac diagnosis. The applicant used the same ICD–9–CM procedure and diagnoses codes as used in the first analysis, but used the following ICD–9–CM procedure codes to identify cases that had an iliac procedure: 39.79 (Other endovascular procedures on other vessels) in combination with 39.29 (Other (peripheral) vascular shunt or bypass), 39.79 in combination with 39.90 (Insertion of non-drug-eluting peripheral (non-coronary) vessel stent(s)) without 39.29, 39.90 in combination with 00.41 (Procedure on two vessels), 00.46 (Insertion of two vascular stents), and 00.47 (Insertion of three vascular stents) without 39.79 and 39.29. The applicant noted that the expected distribution of cases for the GORE IBE device is that 20 percent of the cases would map to MS–DRG 268 and 80 percent of the cases would map to MS–DRG 269. Because this analysis represents cases that had an actual iliac procedure, the applicant applied this distribution to the cases. The applicant then followed the same methodology above and removed charges for the prior technology and resources related to the prior technology, standardized the charges, and then added charges related to the GORE IBE device. Based on the FY 2016 IPPS/LTCH PPS Table 10 thresholds, the average case-weighted threshold amount was $113,015. The applicant computed an inflated average standardized case-weighted charge per case of $138,179. Because the inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

With regard to the second analysis, the applicant imputed the distribution of cases. We are not sure how the applicant determined which cases would map to MS–DRG 268 or MS–DRG 269, if the distribution was imputed. Also, the applicant did not disclose how many cases were found in the claims data after filtering the case volume using ICD–9–CM procedure codes identifying cases that had an iliac procedure. We are inviting public comments on whether the GORE IBE device meets the cost criterion, including with regard to the concerns we have raised.

With regard to the substantial clinical improvement criterion, the applicant indicated that current treatment approaches have substantial risks of complications that can negatively impact quality of life. Available treatment methods that do not preserve internal iliac artery perfusion increase risks for negative clinical outcomes; compared to methods that preserve the internal iliac artery, those that use contralateral hypogastric embolization result in a higher incidence of buttock claudication (15–55 percent), sexual dysfunction (5–45 percent), ischemia of the colon (2.6 percent), and rarely, ischemia of the spine. The applicant cited the "12–04" study,[16] which the applicant suggested showed the GORE IBE device to have 0 percent rates of buttock claudication, new onset erectile dysfunction, colonic ischemia, and spinal cord ischemia. The applicant also suggested that the 12–04 study showed the GORE IBE device to have reduced procedure time, reduced fluoroscopy time, reduced reintervention rates, and increased patency rates. The applicant asserted that because the GORE IBE device preserves flow to the internal iliac artery, the risk of complications is reduced, which represents a substantial clinical improvement relative to current treatment approaches. The applicant also stated that, compared with historical data for procedures done using contralateral hypogastric embolization, the GORE IBE device is associated with reduced procedure time, reduced fluoroscopy time, reduced reintervention rates, reduced incidence of aneurysm enlargement, and improved patency rates.

The applicant submitted several research articles with its application, which consisted of a few very small case series of 23 total patients published,[17] [18] [19] as well as some abstracts of other case series. These publications describe the procedural results of using the device, with angiographic endpoints, and demonstrate the feasibility of insertion. The applicant also indicated that other treatment approaches, including open surgery, are done infrequently, while other approaches are not approved for this purpose. Therefore, the applicant indicated that it would be impractical to conduct comparative studies.

After reviewing the information provided by the applicant, we have the following concerns: We are concerned about the lack of clinical studies comparing the GORE IBE device with alternative methods of treatment, and note that the application did not provide data that supported its assertions that the GORE IBE device is associated with reduced procedure time, reduced fluoroscopy time, reduced reintervention rates, reduced incidence of aneurysm enlargement, and improved patency rates. We also note that the applicant's assertions about decreased rates of complications appear to compare a small number of published cases of the use of the GORE IBE device with complication rates cited in the literature, which does not indicate whether there is a valid basis for comparison. We are inviting public comments on whether the GORE IBE device meets the substantial clinical improvement criterion.

We did not receive any written public comments in response to the February 2016 New Technology Town Hall meeting regarding this application for new technology add-on payments.

i. Vistogard™ (Uridine Triacetate)

BTG International Inc., submitted an application for new technology add-on payments for the Vistogard™ for FY 2017. Vistogard™ (Uridine Triacetate) was developed as an antidote to Fluorouracil toxicity. Chemotherapeutic agent 5-fluorouracil (5–FU) is used to treat specific solid tumors. It acts upon deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) in the body, as uracil is a naturally occurring building block for genetic material. Fluorouracil is a fluorinated pyrimidine. As a chemotherapy agent, Fluorouracil is absorbed up by cells and causes the cell to metabolize into byproducts that are toxic and used to destroy cancerous cells. The byproducts fluorodoxyuridine monophosphate (F-dUMP) and floxuridine triphosphate (FUTP) are believed to do the following: Reduce DNA synthesis, lead to DNA fragmentation, and disrupt RNA synthesis. Fluorouracil is used to treat a variety of solid tumors such as colorectal, head and neck, breast, and ovarian cancer. With different tumor treatments, different dosages, and different dosing schedules, there is a risk for toxicity in these patients.

Patients may suffer from fluorouracil toxicity/death if 5–FU is delivered in slight excess or at faster infusion rates than prescribed. The cause of overdose can happen for a variety of reasons including: Pump malfunction, incorrect pump programming or miscalculated doses, and accidental or intentional ingestion.

According to the applicant, current treatment for fluorouracil toxicity is supportive care, including discontinuation of the drug, hydration, filgrastim for neutropenia, as well as antibiotics, antiemetics, and treatments that are required for potential gastrointestinal and cardiovascular compromise. Vistogard™ is an antidote to Fluorouracil toxicity and is a pro-drug of uridine. Once the drug is metabolized into uridine, it competes with the toxic byproduct FUTP in binding to RNA, thus reducing the impact FUTP has on cell death.

With regard to the newness criterion, Vistogard™ received FDA approval on December 11, 2015. The applicant noted that Vistogard™ is the first FDA approved antidote used to reverse fluorouracil toxicity. Currently, there are no ICD–10–CM procedure codes that uniquely identify the use of Vistogard™. The applicant presented an application at the March 9–10, 2016 meeting of the ICD–10 Coordination and Maintenance Committee for a unique ICD–10–PCS procedure code to identify the use of Vistogard™. If approved, the code will be effective on October 1, 2016 (FY 2017). More information on this request can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Coding/ICD10ProviderDiagnosticCodes/ICD-10-CM-C-and-M-Meeting-Materials.html.*

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[16] DeRubertis BG, Quinones-Baldrich WJ, Greenberg JI, Jimenez JC, Lee JT. Results of a double-barrel technique with commercially available devices for hypogastric preservation during aortoilac endovascular abdominal aortic aneurysm repair. J Vasc Surg 2012;56:1252–1259.

[17] DeRubertis BG, Quinones-Baldrich WJ, Greenberg JI, Jimenez JC, Lee JT. Results of a double-barrel technique with commercially available devices for hypogastric preservation during aortoilac endovascular abdominal aortic aneurysm repair. J Vasc Surg 2012;56:1252–1259.

[18] Ferrer C, De Crescenzo F, Coscarella C, Cao P. Early experience with the Excluder(R) iliac branch endoprosthesis. J Cardiovasc Surg 2014;55:679–683.

[19] Schönhofer S, Mansour R, Ghotbi R. Initial results of the management of aortoiliac aneurysms with GORE(R) Excluder(R) iliac branched endoprosthesis. J Cardiovasc Surg 2015;56:883–888.

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered "new" for purposes of new technology add-on payments.

With regard to the first criterion, whether the product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant stated that Vistogard™ is the first FDA-approved antidote used to reverse fluorouracil toxicity. The applicant maintained that Vistogard™ has a unique mechanism of action that is not comparable to any other drug's mechanism of action that is currently available on the U.S. market. The applicant described in technical detail how the novel and unique mechanism of action provides bioavailable uridine, a direct biochemical antagonist of 5–FU toxicity; quickly absorbs into the gastrointestinal tract due to its lipophilic nature; in normal cells, stops the process of cell damage and cell destruction caused by 5–FU and counteracts the effects of 5–FU toxicity; protects normal cells and allows recovery from damage caused by 5–FU, without interfering with the primary antitumor mechanism of 5–FU; and uses uridine derived from Vistogard™ to convert it into uridine triphosphate (UTP), which competes with FUTP for incorporation into RNA, preventing further cell destruction and dose-limiting toxicities.

With regard to the second criterion, whether the product is assigned to the same or a different MS–DRG, the applicant noted that Xuriden (uridine triacetate) was also approved by the FDA on September 8, 2015, as a pyrimidine analog for uridine replacement indicated for the treatment of hereditary orotic aciduria (HOA). According to the applicant, HOA is a rare, potentially life-threatening, genetic disorder in which patients (primarily pediatric patients) lack the ability to synthesize adequate amounts of uridine and consequently can suffer from hematologic abnormalities, failure to thrive, a range of developmental delays, and episodes of crystalluria leading to obstructive uropathy. The applicant stated that, although Xuriden is approved as a chronic, once daily medication (not to exceed 8 grams) that is administered orally in the patient's home and also used to replace uridine, Xuriden is not administered in a hospital setting and cases involving the use of Xuriden would not be assigned to the same MS–DRGs associated with the use of Vistogard™ in the treatment of patients experiencing 5–FU overdose or severe toxicity. Therefore, the applicant maintained that no other technology similar to Vistogard™ would map to the same MS–DRGs as cases involving the use of Vistogard™.

With regard to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, similar to above, the applicant maintained that Vistogard™ is the first FDA approved antidote to reverse fluorouracil toxicity and, therefore, no other technology treats this disease or patient population to reverse fluorouracil toxicity. Therefore, the applicant believed that Vistogard™ is not substantially similar to any other currently approved technology. We are inviting public comments on whether Vistogard™ is substantially similar to existing technologies and whether it meets the newness criterion.

With regard to the cost criterion, the applicant searched the claims data from the 2013 and 2014 Inpatient SAFs for cases that may be eligible for treatment involving Vistogard™. Specifically, the applicant searched for cases reporting a primary ICD–9–CM diagnosis code for colorectal cancer, head and neck cancer, gastric cancers and pancreatic cancer. The applicant further narrowed the potential target patient population by identifying cases reporting toxicity due to an antineoplastic. In order to include only patients diagnosed with severe toxicity that would be eligible for treatment using Vistogard™, using revenue center codes and ICD–9–CM V codes, the applicant included an additional cohort of cases representing patients admitted from the emergency department, an observation unit, another short-term, acute care hospital, or who have received chemotherapy treatment during the inpatient stay included on the claim. Because 5–FU toxicity is associated with a high mortality rate, the applicant identified a subgroup of patients diagnosed with chemotherapy toxicity who expired during their inpatient visit or within 7 days of discharge. The applicant provided two analyses to determine that the technology meets the cost criterion: One analysis of patients that experienced toxicity with mortality and a second analysis using the broader chemotherapy toxicity cohort, which includes patients who did not expire. The table below provides the diagnosis codes and information the applicant used to identify cases for both of these analyses.

Criterion	ICD–9 code	Description
Colorectal, head and neck, gastric, or pancreatic cancer (at least one code).	153.x	Malignant neoplasm of colon.
	154.x	Malignant neoplasm of rectum, rectosigmoid junction, and anus.
	171.0	Malignant neoplasm of head, face, and neck.
	151.x	Malignant neoplasm of stomach.
	157.x	Malignant neoplasm of pancreas.
Toxicity due to an antineoplastic (at least one code)	963.1	Poisoning by antineoplastic and immunosuppressive drugs.
	E933.1	Antineoplastic and immunosuppressive drugs causing adverse effects in therapeutic use.
Admission to Inpatient Setting Admitted from ED	Revenue Center	Revenue Center Codes 450, 451, 452, 456, 459.
or observation unit	Revenue Center	Revenue Center Codes 760, 761, 762, 769.
or short-term, acute care hospital	N/A	Source of admission code = "4" "Transfer from hospital (Different facility)".
or received chemotherapy during inpatient stay	V58.0	Encounter or admission for radiation.
	V58.11	Encounter for antineoplastic chemotherapy.
	V58.12	Encounter for antineoplastic immunotherapy (Must be primary diagnosis on the claim).

Criterion	ICD–9 code	Description
Expired during inpatient stay or within seven days of discharge (at least one code) [a].	N/A .... N/A	Determined by patient discharge status code. If date of death in 100 percent Denominator File pertaining to the year of the claim was within 7 days of claim discharge date.

[a] Required only for toxicity with mortality cohort.
Source: KNG Health analysis of 2013–2014 100% Inpatient Standard Analytic Files and 2013–2014 100% Denominator Files.

Under the first analysis, the applicant found 76 cases with 18.42 percent of those cases mapping to MS–DRG 871 (Septicemia or Severe Sepsis without Mechanical Ventilation > 96 hours with MCC), and the remaining number of cases mapping to MS–DRGs with less than 11 cases. According to the applicant, the results of the analysis of the MS–DRGs with less than 11 cases could not be discussed separately because of the small sample sizes. The applicant believed that it was unnecessary to remove any charges for other previously used technologies because although Vistogard™ is singular in its ability to treat 5–FU toxicity, the associated charges for palliative care would continue to be necessary to treat the symptoms of the toxicity, even though it is possible that the use of Vistogard™ may reduce a patient's hospital length of stay. To update the charge data to the current fiscal year, the applicant inflated the charges based on the charge inflation factor of 1.048116 in the FY 2016 IPPS/LTCH proposed rule (80 FR 24632). A 1-year inflation factor was applied three times for FY 2013 claims and two times for FY 2014 claims, inflating all claims to FY 2016. This resulted in an inflated average standardized case-weighted charge per case of $51,451. Using the FY 2016 IPPS Table 10 thresholds, the average case-weighted threshold amount was $46,233 (all calculations above were performed using unrounded numbers). The applicant noted that the inflated average standardized case-weighted charge per case exceeded the average case-weighted threshold amount without including charges for Vistogard™. Therefore, because the inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

Under the second analysis, the applicant used the same methodology it used in its first analysis, except that the analysis included cases representing patients who did not expire. The applicant found 879 cases with 8.53 percent of those cases mapping to MS–DRG 392 (Esophagitis, Gastroenteritis and Miscellaneous Digestive System Disorders without MCC), and the remaining number of cases spread across several MS–DRGs. The inflated average standardized case-weighted charge per case was $42,708. Using the FY 2016 IPPS Table 10 thresholds, the average case-weighted threshold amount was $42,377 (all calculations above were performed using unrounded numbers). Similar to the results of the first analysis, the applicant noted that the inflated average standardized case-weighted charge per case exceeded the average case-weighted threshold amount without including charges for Vistogard™. Therefore, because the inflated average standardized case-weighted charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology also meets the cost criterion under the second analysis.

We note that the applicant used the inflation factor of 1.048116 from the FY 2016 IPPS/LTCH proposed rule instead of the inflation factor of 1.037616 from the FY 2016 IPPS/LTCH final rule (80 FR 49784). We believe that the applicant should use the most recent data available, which is the inflation factor from the final rule. The inflation factor from the FY 2016 IPPS/LTCH final rule is lower than the inflation factor from the proposed rule. However, the difference between these two factors is marginal. Also, as the applicant noted, it did not include charges for Vistogard™ in its analysis. Therefore, we believe that it is likely that the applicant would still meet the cost criterion under both analyses even if it used the lower inflation factor from the FY 2016 final rule. We are inviting public comments on whether Vistogard™ meets the cost criterion under both analyses.

With regard to substantial clinical improvement, the applicant maintained that Vistogard™ represents a substantial clinical improvement. The applicant noted that Vistogard™ is the first and only antidote indicated to treat adult and pediatric patients following a fluorouracil overdose, regardless of the presence of symptoms or whether a patient exhibits early-onset, severe or life-threatening toxicity within 96 hours following the conclusion of fluorouracil or capecitabine administration. The applicant provided data from two studies (Study 1, an open-label, single arm, multi-center expanded access study and Study 2, an open-label, single arm, multi-center emergency use study), which combined enrolled 135 patients. The applicant noted that 130 patients treated with Vistogard™ survived through the 30-day treatment and observation period (95 percent Confidence Interval: 0.92, 0.99). Of the 135 patients, 30 percent were 65 years old and older, including 11 percent of patients who were 75 years old and older.

According to the applicant, the studies' results demonstrate that Vistogard™ reduced the incidence, severity and virulence of toxicities associated with 5–FU toxicity due to overdose or rapid onset. Specifically, the applicant noted the following results:

- Vistogard™ ameliorated the progression of mucositis, leukopenia and thrombocytopenia; leukopenia and thrombocytopenia were resolved in almost all patients by the 4th week, indicating recovery of the hematopoietic system; mucositis also was resolved in almost all patients within the 30-day observation period with the incidence of serious (Grade 3 or 4) mucositis being very low; and no grade 4 mucositis was observed in any patients who received treatment using Vistogard™ within 96 hours after 5–FU.
- Thirty-eight percent of patients who experienced 5–FU overdose were able to resume chemotherapy treatment in less than 30 days after 5–FU toxicity, with the majority of these patients resuming treatment within 21 days. According to the applicant, 21 percent of the patients who presented with rapid onset of serious toxicities resumed chemotherapy treatment (typically with a different agent than 5–FU) in less than 30 days, with an overall median time to resumption of chemotherapy of 19 days.
- The safety and tolerability profile of Vistogard™ is consistent with what would be expected for patients diagnosed with cancer following 5–FU chemotherapy treatment, but is generally less in severity and incidence when compared to what would be expected with patients who experience a 5–FU overdose. Specifically, during Study 1, there were no patients that

discontinued uridine triacetate treatment as a result of adverse events, and during Study 2, three patients discontinued uridine triacetate treatment as a result of adverse events, one of which was considered possibly related to uridine triacetate (nausea and vomiting).

We are inviting public comments on whether Vistogard™ meets the substantial clinical improvement criterion.

We did not receive any written public comments in response to the February 2016 New Technology Town Hall meeting regarding this application for new technology add-on payments.

III. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

A. Background

1. Legislative Authority

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary adjust the standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. We currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). A discussion of the proposed FY 2017 hospital wage index based on the statistical areas appears under sections III.A.2. and G. of the preamble of this proposed rule.

Section 1886(d)(3)(E) of the Act requires the Secretary to update the wage index annually and to base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. (CMS collects these data on the Medicare cost report, CMS Form 2552–10, Worksheet S–3, Parts II, III, and IV. The OMB control number for approved collection of this information is 0938–0050.) This provision also requires that any updates or adjustments to the wage index be made in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. The proposed adjustment for FY 2017 is discussed in section II.B. of the Addendum to this proposed rule.

As discussed in section III.J. of the preamble of this proposed rule, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating IPPS payment amounts. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B), 1886(d)(8)(C), and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The proposed budget neutrality adjustment for FY 2017 is discussed in section II.A.4.b. of the Addendum to this proposed rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. A discussion of the occupational mix adjustment that we are proposing to apply to the FY 2017 wage index, appears under sections III.E.3. and F. of the preamble of this proposed rule.

2. Core-Based Statistical Areas (CBSAs) Revisions for the Proposed FY 2017 Hospital Wage Index

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on OMB-established Core-Based Statistical Areas (CBSAs). The current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. OMB Bulletin No. 13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census, and provided guidance on the use of the delineations of these statistical areas using standards published on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252). We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) for a full discussion of our implementation of the new OMB labor market area delineations beginning with the FY 2015 wage index.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provides updates to and supersedes OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provides detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. The complete list of statistical areas incorporating these changes is provided in the attachment to OMB Bulletin No. 15–01. According to OMB, "[t]his bulletin establishes revised delineations for the Nation's Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas. The bulletin also provides delineations of Metropolitan Divisions as well as delineations of New England City and Town Areas." A copy of this bulletin may be obtained on the Web site at: *https://www.whitehouse.gov/omb/bulletins_default.*

OMB Bulletin No. 15–01 made the following changes that are relevant to the IPPS wage index:

- Garfield County, OK, with principal city Enid, OK, which was a Micropolitan (geographically rural) area, now qualifies as an urban new CBSA 21420 called Enid, OK.
- The county of Bedford City, VA, a component of the Lynchburg, VA CBSA 31340, changed to town status and is added to Bedford County. Therefore, the county of Bedford City (SSA State county code 49088, FIPS State County Code 51515) is now part of the county of Bedford, VA (SSA State county code 49090, FIPS State County Code 51019). However, the CBSA remains Lynchburg, VA, 31340.
- The name of Macon, GA, CBSA 31420, as well as a principal city of the Macon-Warner Robins, GA combined statistical area, is now Macon-Bibb County, GA. The CBSA code remains as 31420.

We believe that it is important for the IPPS to use the latest labor market area delineations available as soon as is reasonably possible in order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions (79 FR 28055). Therefore, we are proposing to implement these revisions, effective October 1, 2016, beginning with the FY 2017 wage indexes. We are proposing to use these new definitions to calculate area wage indexes in a manner that is generally consistent with the CBSA-based methodologies finalized in the FY 2005 and the FY 2015 IPPS final rules. For FY

2017, Tables 2 and 3 for this proposed rule and the County to CBSA Crosswalk File and Urban CBSAs and Constituent Counties for Acute Care Hospitals File posted on the CMS Web site reflect these CBSA changes. We are inviting public comments on these proposals.

B. Worksheet S–3 Wage Data for the Proposed FY 2017 Wage Index

The proposed FY 2017 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2013 (the FY 2016 wage indexes were based on data from cost reporting periods beginning during FY 2012).

1. Included Categories of Costs

The proposed FY 2017 wage index includes all of the following categories of data associated with costs paid under the IPPS (as well as outpatient costs):

- Salaries and hours from short-term, acute care hospitals (including paid lunch hours and hours associated with military leave and jury duty);
- Home office costs and hours;
- Certain contract labor costs and hours, which include direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services, and certain contract indirect patient care services (as discussed in the FY 2008 final rule with comment period (72 FR 47315 through 47317)); and
- Wage-related costs, including pension costs (based on policies adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51586 through 51590)) and other deferred compensation costs.

2. Excluded Categories of Costs

Consistent with the wage index methodology for FY 2016, the proposed wage index for FY 2017 also excludes the direct and overhead salaries and hours for services not subject to IPPS payment, such as skilled nursing facility (SNF) services, home health services, costs related to GME (teaching physicians and residents) and certified registered nurse anesthetists (CRNAs), and other subprovider components that are not paid under the IPPS. The proposed FY 2017 wage index also excludes the salaries, hours, and wage-related costs of hospital-based rural health clinics (RHCs), and Federally qualified health centers (FQHCs) because Medicare pays for these costs outside of the IPPS (68 FR 45395). In addition, salaries, hours, and wage-related costs of CAHs are excluded from the wage index for the reasons explained in the FY 2004 IPPS final rule (68 FR 45397 through 45398).

3. Use of Wage Index Data by Suppliers and Providers Other Than Acute Care Hospitals Under the IPPS

Data collected for the IPPS wage index also are currently used to calculate wage indexes applicable to suppliers and other providers, such as SNFs, home health agencies (HHAs), ambulatory surgical centers (ASCs), and hospices. In addition, they are used for prospective payments to IRFs, IPFs, and LTCHs, and for hospital outpatient services. We note that, in the IPPS rules, we do not address comments pertaining to the wage indexes of any supplier or provider except IPPS providers and LTCHs. Such comments should be made in response to separate proposed rules for those suppliers and providers.

C. Verification of Worksheet S–3 Wage Data

The wage data for the proposed FY 2017 wage index were obtained from Worksheet S–3, Parts II and III of the Medicare cost report (Form CMS–2552–10, OMB control number 0938–0050) for cost reporting periods beginning on or after October 1, 2012, and before October 1, 2013. For wage index purposes, we refer to cost reports during this period as the "FY 2013 cost report," the "FY 2013 wage data," or the "FY 2013 data." Instructions for completing the wage index sections of Worksheet S–3 are included in the Provider Reimbursement Manual (PRM), Part 2 (Pub. No. 15–2), Chapter 40, Sections 4005.2 through 4005.4. The data file used to construct the proposed FY 2017 wage index includes FY 2013 data submitted to us as of February 29, 2016. As in past years, we performed an extensive review of the wage data, mostly through the use of edits for reasonableness designed to identify aberrant data.

We asked our MACs to revise or verify data elements that result in specific edit failures. For the proposed FY 2017 wage index, we identified and excluded 62 providers with aberrant data that should not be included in the proposed wage index. Of these 62 providers that we excluded from the proposed wage index, 47 have data that we do not expect to change such that the data would be included in the final wage index (for example, among the reasons these providers were excluded is they are low Medicare utilization providers, they closed and failed edits for reasonableness, or they have extremely high or low average hourly wages that are atypical for their CBSAs). If data elements for some of these providers are corrected, we intend to include those providers in the calculation of the final FY 2017 wage index. We also adjusted certain aberrant data and included these data in the proposed wage index. For example, in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in accordance with policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967).

In constructing the proposed FY 2017 wage index, we included the wage data for facilities that were IPPS hospitals in FY 2013, inclusive of those facilities that have since terminated their participation in the program as hospitals, as long as those data did not fail any of our edits for reasonableness. We believed that including the wage data for these hospitals is, in general, appropriate to reflect the economic conditions in the various labor market areas during the relevant past period and to ensure that the current wage index represents the labor market area's current wages as compared to the national average of wages. However, we excluded the wage data for CAHs as discussed in the FY 2004 IPPS final rule (68 FR 45397 through 45398). For the this proposed rule, we removed 3 hospitals that converted to CAH status on or after February 5, 2015, the cut-off date for CAH exclusion from the FY 2016 wage index, and through and including January 22, 2016, the cut-off date for CAH exclusion from the FY 2017 wage index. After removing hospitals that converted to CAH status, we calculated the proposed FY 2017 wage index based on 3,345 hospitals.

For the proposed FY 2017 wage index, we allotted the wages and hours data for a multicampus hospital among the different labor market areas where its campuses are located in the same manner that we allotted such hospitals' data in the FY 2016 wage index (80 FR 49489 through 49491). Table 2, which contains the proposed FY 2017 wage index associated with proposed rule (available via the Internet on the CMS Web site), includes separate wage data for the campuses of 9 multicampus hospitals.

D. Method for Computing the Proposed FY 2017 Unadjusted Wage Index

The method used to compute the proposed FY 2017 wage index without an occupational mix adjustment follows the same methodology that we used to compute the FY 2012, FY 2013, FY 2014, FY 2015, and FY 2016 final wage indexes without an occupational mix adjustment (76 FR 51591 through 51593, 77 FR 53366 through 53367, 78 FR 50587 through 50588, 79 FR 49967 and

80 FR 49491 through 49492, respectively).

As discussed in the FY 2012 IPPS/LTCH PPS final rule, in "Step 5," for each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2012, through April 15, 2014, for private industry hospital workers from the BLS' *Compensation and Working Conditions.* We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we are not proposing any changes to the usage for FY 2017. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated in the following table.

MIDPOINT OF COST REPORTING PERIOD

After	Before	Adjustment factor
10/14/2012	11/15/2012	1.02321
11/14/2012	12/15/2012	1.02183
12/14/2012	01/15/2013	1.02040
01/14/2013	02/15/2013	1.01894
02/14/2013	03/15/2013	1.01743
03/14/2013	04/15/2013	1.01592
04/14/2013	05/15/2013	1.01443
05/14/2013	06/15/2013	1.01297
06/14/2013	07/15/2013	1.01152
07/14/2013	08/15/2013	1.01006
08/14/2013	09/15/2013	1.00859
09/14/2013	10/15/2013	1.00711
10/14/2013	11/15/2013	1.00561
11/14/2013	12/15/2013	1.00408
12/14/2013	01/15/2014	1.00260
01/14/2014	02/15/2014	1.00124
02/14/2014	03/15/2014	1.00000
03/14/2014	04/15/2014	0.99878

For example, the midpoint of a cost reporting period beginning January 1, 2013, and ending December 31, 2013, is June 30, 2013. An adjustment factor of 1.01152 would be applied to the wages of a hospital with such a cost reporting period.

Using the data as previously described, the proposed FY 2017 national average hourly wage (unadjusted for occupational mix) is $41.1026.

Previously, we would also provide a Puerto Rico overall average hourly wage. As discussed in section IV.A. of the preamble of this proposed rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we calculated a Puerto Rico-specific wage index that was applied to the labor share of the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), enacted on December 18, 2015, amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act, as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need to calculate a Puerto Rico-specific average hourly wage and wage index. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national average hourly wage (unadjusted for occupational mix) (which would be $41.1026 for this FY 2017 proposed rule) and the national wage index, which is applied to the national labor share of the national standardized amount. Accordingly, for FY 2017, we are not proposing a Puerto Rico-specific overall average hourly wage or wage index.

E. Proposed Occupational Mix Adjustment to the FY 2017 Wage Index

As stated earlier, section 1886(d)(3)(E) of the Act provides for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.

1. Use of 2013 Occupational Mix Survey for the FY 2017 Proposed Wage Index

Section 304(c) of Public Law 106–554 amended section 1886(d)(3)(E) of the Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. We collected data in 2013 to compute the occupational mix adjustment for the FY 2016, FY 2017, and FY 2018 wage indexes. A new measurement of occupational mix is required for FY 2019.

The 2013 survey included the same data elements and definitions as the previous 2010 survey and provided for the collection of hospital-specific wages and hours data for nursing employees for calendar year 2013 (that is, payroll periods ending between January 1, 2013 and December 31, 2013). We published the 2013 survey in the **Federal Register** on February 28, 2013 (78 FR 13679 through 13680). This survey was approved by OMB on May 14, 2013, and is available on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/Medicare-Wage-Index-Occupational-Mix-Survey2013.html.* The 2013 Occupational Mix Survey Hospital Reporting Form CMS–10079 for the Wage Index Beginning FY 2016 (in Excel format) is available on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/Medicare-Wage-Index-Occupational-Mix-Survey2013.html.* Hospitals were required to submit their completed 2013 surveys to their MACs by July 1, 2014. The preliminary, unaudited 2013 survey data were posted on the CMS Web site on July 11, 2014. As with the Worksheet S–3, Parts II and III cost report wage data, we asked our MACs to revise or verify data elements in hospitals' occupational mix surveys that result in certain edit failures.

2. Development of the 2016 Medicare Wage Index Occupational Mix Survey for the FY 2019 Wage Index

As stated earlier, section 304(c) of Public Law 106–554 amended section 1886(d)(3)(E) of the Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. We collected data in 2013 to compute the occupational mix adjustment for the FY 2016, FY 2017, and FY 2018 wage indexes. A new measurement of occupational mix is required for FY 2019. The FY 2019 occupational mix adjustment will be based on a new calendar year (CY) 2016 survey. The CY 2016 survey (CMS Form CMS–10079) is currently awaiting approval by OMB, and can be accessed at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201512-0938-011*.

3. Calculation of the Proposed Occupational Mix Adjustment for FY 2017

For FY 2017, we are proposing to calculate the occupational mix adjustment factor using the same methodology that we used for the FY 2012, FY 2013, FY 2014, FY 2015, and FY 2016 wage indexes (76 FR 51582 through 51586, 77 FR 53367 through 53368, 78 FR 50588 through 50589, 79 FR 49968, and 80 FR 49492 through 49493, respectively) and to apply the occupational mix adjustment to 100 percent of the FY 2017 wage index. Because the statute requires that the Secretary measure the earnings and paid hours of employment by occupational category not less than once every 3 years, all hospitals that are subject to payments under the IPPS, or any hospital that would be subject to the IPPS if not granted a waiver, must complete the occupational mix survey, unless the hospital has no associated cost report wage data that are included in the FY 2017 wage index. For the FY 2017 wage index, we are using the Worksheet S–3, Parts II and III wage data of 3,345 hospitals, and we are using the occupational mix surveys of 3,143 hospitals for which we also have Worksheet S–3 wage data, which represents a "response" rate of 94 percent (3,143/3,345). For the proposed FY 2017 wage index in this proposed rule, we applied proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data in the same manner that we applied proxy data for such hospitals in the FY 2012 wage index occupational mix adjustment (76 FR 51586).

F. Analysis and Implementation of the Proposed Occupational Mix Adjustment and the Proposed FY 2017 Occupational Mix Adjusted Wage Index

1. Analysis of the Occupational Mix Adjustment and the Occupational Mix Adjusted Wage Index

As discussed in section III.E. of the preamble of this proposed rule, for FY 2017, we are proposing to apply the occupational mix adjustment to 100 percent of the FY 2017 wage index. We calculated the proposed occupational mix adjustment using data from the 2013 occupational mix survey data, using the methodology described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51582 through 51586).

Using the occupational mix survey data and applying the occupational mix adjustment to 100 percent of the FY 2017 wage index results in a proposed national average hourly wage of $41.0651. Previously, we would also provide a Puerto Rico overall average hourly wage. As discussed in section IV.A. of the preamble of this proposed rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we calculated a Puerto Rico-specific wage index that was applied to the labor-related share of the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), enacted on December 18, 2015, amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount as of January 1, 2016 under section 1886(d)(9)(E) of the Act, as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need to calculate a Puerto Rico-specific average hourly wage and wage index. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national average hourly wage (adjusted for occupational mix) (which would be $41.0651 for this FY 2017 IPPS proposed rule) and the national wage index, which is applied to the national labor share of the national standardized amount. Accordingly, for FY 2017, we are not proposing a Puerto Rico-specific overall average hourly wage or wage index.

The proposed FY 2017 national average hourly wages for each occupational mix nursing subcategory as calculated in Step 2 of the occupational mix calculation are as follows:

Occupational mix nursing subcategory	Average hourly wage
National RN	$38.814164598
National LPN and Surgical Technician	22.733613839
National Nurse Aide, Orderly, and Attendant	15.94875556
National Medical Assistant	18.058859076
National Nurse Category	32.844074591

The proposed national average hourly wage for the entire nurse category as computed in Step 5 of the occupational mix calculation is $32.844074591. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of greater than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of less than 1.0. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of less than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of greater than 1.0.

Based on the 2013 occupational mix survey data, we determined (in Step 7 of the occupational mix calculation) that the national percentage of hospital employees in the nurse category is 42.6 percent, and the national percentage of hospital employees in the all other occupations category is 57.4 percent. At the CBSA level, the percentage of hospital employees in the nurse category ranged from a low of 25.6 percent in one CBSA to a high of 80.5 percent in another CBSA.

We compared the proposed FY 2017 occupational mix adjusted wage indexes for each CBSA to the proposed unadjusted wage indexes for each CBSA. As a result of applying the occupational mix adjustment to the wage data, the proposed wage index values for 221 (54.2 percent) urban areas and 24 (51.1 percent) rural areas would increase. One hundred and three (25.2 percent) urban areas would increase by greater than or equal to 1 percent but less than 5 percent, and 6 (1.5 percent) urban areas would increase by 5 percent or more. Nine (19.1 percent) rural areas would increase by greater than or equal to 1 percent but less than 5 percent, and no rural areas would increase by 5 percent or more. However, the proposed wage index values for 185 (45.3 percent) urban areas and 23 (48.9 percent) rural areas would decrease. Eighty-nine (21.8 percent) urban areas would decrease by greater than or equal to 1 percent but less than 5 percent, and no urban area would decrease by 5 percent or more. Seven (14.9 percent) rural areas would decrease by greater than or equal to 1 percent and less than 5 percent, and no rural areas would decrease by 5 percent or more. The largest positive impacts would be 17.4 percent for an urban area and 2.9 percent for a rural area. The largest negative impacts would be 4.9 percent for an urban area and 2.1 percent for a rural area. Two urban areas' wage indexes, but no rural area wage indexes, would remain unchanged by application of the proposed occupational mix adjustment. These results indicate that a larger percentage of urban areas (54.2 percent) would benefit from the proposed occupational mix adjustment than would rural areas (51.1 percent).

G. Transitional Wage Indexes

1. Background

In the FY 2015 IPPS/LTCH PPS proposed rule and final rule (79 FR 28060 and 49957, respectively), we stated that, overall, we believed implementing the new OMB labor market area delineations would result in wage index values being more representative of the actual costs of labor in a given area. However, we recognized that some hospitals would experience decreases in wage index values as a result of the implementation of these new OMB labor market area delineations. We also realized that some hospitals would have higher wage index values due to the implementation of the new OMB labor market area delineations.

The FY 2015 IPPS/LTCH PPS final rule (79 FR 49957) explained the methodology utilized in implementing prior transition periods when adopting changes that have significant payment implications, particularly large negative impacts. Specifically, for FY 2005, in the FY 2005 IPPS final rule (69 FR 49032 through 49034), we provided transitional wage indexes when the OMB definitions were implemented after the 2000 Census. The FY 2015 IPPS/LTCH PPS final rule (79 FR 49957 through 49962) established similar transition methodologies to mitigate any negative payment impacts experienced by hospitals due to our adoption of the new OMB labor market area delineations for FY 2015.

As finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49957 through 49960) and as discussed below, for FY 2017, we will be in the third and final year of two 3-year transition periods for wage index (1) for hospitals that, for FY 2014, were located in an urban county that became rural under the new OMB delineations, and had no form of wage index reclassification or redesignation in place for FY 2015 (that is, MGCRB reclassifications under section 1886(d)(10) of the Act, redesignations under section 1886(d)(8)(B) of the Act, or rural reclassifications under section 1886(d)(8)(E) of the Act); and (2) for hospitals deemed urban under section 1886(d)(8)(B) of the Act where the urban area became rural under the new OMB delineations.

2. Transition for Hospitals in Urban Areas That Became Rural

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49957 through 49959), for hospitals that, for FY 2014, were located in an urban county that became rural under the new OMB delineations, and had no form of wage index reclassification or redesignation in place for FY 2015 (that is, MGCRB reclassifications under section 1886(d)(10) of the Act, redesignations under section 1886(d)(8)(B) of the Act, or rural reclassifications under section 1886(d)(8)(E) of the Act), we adopted a policy to assign them the urban wage index value of the CBSA in which they were physically located for FY 2014 for a period of 3 fiscal years (with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied to the area wage index). FY 2017 will be the third year of this transition policy, and we are not proposing any changes to this policy in this proposed rule. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49957) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49495), we stated our belief that it is appropriate to apply a 3-year transition period for hospitals located in urban counties that would become rural under the new OMB delineations, given the potentially significant payment impacts for these hospitals. We continue to believe that assigning the wage index of the hospitals' FY 2014 area for a 3-year transition is the simplest and most effective method for mitigating negative payment impacts due to the adoption of the new OMB delineations.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49959), we noted that there were situations where a hospital could not be assigned the wage index value of the CBSA in which it geographically was located in FY 2014 because that CBSA split and no longer exists and some or all of the constituent counties were added to another urban labor market area under the new OMB delineations. If the hospital could not be assigned the wage index value of the CBSA in which it was geographically located in FY 2014 because that CBSA split apart and no longer exists, and some or all of its constituent counties were added to another urban labor market area under the new OMB delineations, we established that hospitals located in such counties that became rural under the new OMB delineations were assigned the wage index of the urban labor market area that contained the urban county in their FY 2014 CBSA to which they were closest (with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied). Any such assignment made in FY 2015 and continued in FY 2016 will continue for FY 2017, except as discussed later in this section. We continue to believe this approach minimizes the negative effects of the change in the OMB delineations.

Under the policy adopted in the FY 2015 IPPS/LTCH PPS final rule, if a hospital for FY 2014 was located in an urban county that became rural for FY 2015 under the new OMB delineations and such hospital sought and was granted reclassification or redesignation for FY 2015 or FY 2016, or such hospital seeks and is granted any reclassification or redesignation for FY 2017, the hospital will permanently lose its 3-year transitional assigned wage index status, and will not be eligible to reinstate it. We established the transition policy to assist hospitals if they experience a negative payment impact specifically due to the adoption of the new OMB delineations in FY 2015. If a hospital chooses to forego this transition adjustment by obtaining some form of reclassification or redesignation, we do not believe reinstatement of this transition adjustment would be appropriate. The purpose of the transition adjustment policy is to assist hospitals that may be negatively impacted by the new OMB delineations in transitioning to a wage index based on these delineations. By obtaining a reclassification or redesignation, we believe that the hospital has made the determination that the transition adjustment is not necessary because it has other viable options for mitigating the impact of the transition to the new OMB delineations.

As we did for FY 2015 (79 FR 49959) and FY 2016 (80 FR 49495), with respect to the wage index computation for FY 2017, we will follow our existing policy regarding the inclusion of a hospital's wage index data in the CBSA in which it is geographically located (we refer readers to Step 6 of the method for computing the unadjusted wage index in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51592)). Accordingly, for FY 2017, the wage data of all hospitals receiving this type of 3-year transition adjustment will be included in the statewide rural area in which they are geographically located under the new OMB labor market area delineations. After the 3-year transition period, beginning in FY 2018, these formerly urban hospitals will receive their statewide rural wage index, absent any reclassification or redesignation.

In addition, we established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49959) that the hospitals receiving this 3-year transition because they are in counties that were urban under the FY 2014 CBSA definitions, but are rural under the new OMB delineations, will not be considered urban hospitals. Rather, they will maintain their status as rural hospitals for other payment considerations. This is because our application of a 3-year transitional wage index for these newly rural hospitals only applies for the purpose of calculating the wage index under our adoption of the new OMB delineations.

3. Transition for Hospitals Deemed Urban Under Section 1886(d)(8)(B) of the Act Where the Urban Area Became Rural Under the New OMB Delineations

As discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49959 through 49960) and FY 2016 IPPS/LTCH PPS final rule (80 FR 49495 through 49496), there were some hospitals that, for FY 2014, were geographically located in rural areas but were deemed to be urban under section 1886(d)(8)(B) of the Act. For FY 2015, some of these hospitals redesignated under section 1886(d)(8)(B) of the Act were no longer eligible for deemed urban status under the new OMB delineations, as discussed in detail in section III.H.3. of the preamble of the FY 2015 IPPS/LTCH PPS final rule. Similar to the policy implemented in the FY 2005 IPPS final rule (69 FR 49059), and consistent with the FY 2015 policy we established for other hospitals in counties that were urban and became rural under the new OMB delineations, we finalized a policy to apply a 3-year transition to these hospitals redesignated to urban areas under section 1886(d)(8)(B) of the Act for FY 2014 that are no longer deemed urban under the new OMB delineations and revert to being rural.

For FY 2017, we are not proposing any changes to this policy and will continue the third and final year of the implementation of our policy to provide a 3-year transition adjustment to hospitals that are deemed urban under section 1886(d)(8)(B) of the Act under the FY 2014 labor market area delineations, but are considered rural under the new OMB delineations, assuming no other form of wage index reclassification or redesignation is granted. We assign these hospitals the area wage index value of hospitals reclassified to the urban CBSA (that is, the attaching wage index) to which they were redesignated in FY 2014 (with the rural and imputed floors applied and with the rural floor budget neutrality adjustment applied). If the hospital cannot be assigned the reclassified wage index value of the CBSA to which it was redesignated in FY 2014 because that CBSA was split apart and no longer exists, and some or all of its constituent counties were added to another urban labor market area under the new OMB delineations, such hospitals are assigned the wage index of the hospitals reclassified to the urban labor market area that contained the urban county in their FY 2014 redesignated CBSA to which they were closest. We assign these hospitals the area wage index of hospitals reclassified to a CBSA because hospitals deemed urban under section 1886(d)(8)(B) of the Act are treated as reclassified under current policy, under which such hospitals receive an area wage index that includes wage data of all hospitals reclassified to the area. This wage index assignment will be forfeited if the hospital obtains any form of wage index reclassification or redesignation.

4. Budget Neutrality

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50372 through 50373), for FY 2015, and in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49496), for FY 2016, we applied the 3-year transition wage index adjustments in a budget neutral manner. For FY 2017, we are proposing to apply the 3-year transition adjustments in a budget neutral manner. We are proposing to make an adjustment to the standardized amount to ensure that the total payments, including the effect of the transition provisions, would equal what payments would have been if we would not be providing for any transitional wage indexes under the new OMB delineations. For a complete discussion on the proposed budget neutrality adjustment for FY 2017, we refer readers to section II.A.4.b. of the Addendum to this proposed rule.

H. Proposed Application of the Proposed Rural, Imputed, and Frontier Floors

1. Proposed Rural Floor

Section 4410(a) of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is referred to as the "rural floor." Section 3141 of Public Law 111–148 also requires that a national budget neutrality adjustment be applied in implementing the rural floor. Based on the proposed FY 2017 wage index associated with this proposed rule (which is available via the Internet on the CMS Web site), we estimated that 371 hospitals would receive an increase in their FY 2017 proposed wage index due to the application of the rural floor.

2. Proposed Imputed Floor for FY 2017

In the FY 2005 IPPS final rule (69 FR 49109 through 49111), we adopted the "imputed floor" policy as a temporary 3-year regulatory measure to address concerns from hospitals in all-urban States that have argued that they are disadvantaged by the absence of rural hospitals to set a wage index floor for those States. Since its initial implementation, we have extended the imputed floor policy six times, the last of which was adopted in the FY 2016 IPPS/LTCH PPS final rule and is set to expire on September 30, 2016. (We refer readers to further discussions of the imputed floor in the FY 2014, FY 2015, and FY 2016 IPPS/LTCH PPS final rules (78 FR 50589 through 50590, 79 FR 49969 through 49970, and 80 FR 49497 through 49498, respectively) and to the regulations at 42 CFR 412.64(h)(4).) Currently, there are three all-urban States—Delaware, New Jersey, and Rhode Island—with a range of wage indexes assigned to hospitals in these States, including through reclassification or redesignation. (We refer readers to discussions of geographic reclassifications and redesignations in section III.J. of the preamble of this proposed rule.)

In computing the imputed floor for an all-urban State under the original methodology, which was established beginning in FY 2005, we calculated the ratio of the lowest-to-highest CBSA wage index for each all-urban State as well as the average of the ratios of lowest-to-highest CBSA wage indexes of those all-urban States. We then compared the State's own ratio to the average ratio for all-urban States and whichever is higher is multiplied by the highest CBSA wage index value in the State—the product of which established the imputed floor for the State. As of FY 2012, there were only two all-urban States—New Jersey and Rhode Island—and only New Jersey benefitted under this methodology. Under the previous OMB labor market area delineations, Rhode Island had only one CBSA (Providence-New Bedford-Fall River, RI–MA) and New Jersey had 10 CBSAs. Therefore, under the original methodology, Rhode Island's own ratio equaled 1.0, and its imputed floor was equal to its original CBSA wage index value. However, because the average ratio of New Jersey and Rhode Island was higher than New Jersey's own ratio, this methodology provided a benefit for New Jersey, but not for Rhode Island.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53368 through 53369), we retained the imputed floor calculated under the original methodology as discussed above, and established an alternative methodology for computing the imputed floor wage index to address the concern that the original imputed floor methodology guaranteed a benefit for one all-urban State with multiple wage indexes (New Jersey) but could not benefit the other all-urban State (Rhode Island). The alternative methodology for calculating the imputed floor was established using data from the application of the rural floor policy for FY 2013. Under the alternative methodology, we first determined the average percentage difference between the post-reclassified, pre-floor area wage index and the post-reclassified, rural floor wage index (without rural floor budget neutrality applied) for all CBSAs receiving the rural floor. (Table 4D associated with the FY 2013 IPPS/LTCH PPS final rule (which is available via the Internet on the CMS Web site) included the CBSAs receiving a State's rural floor wage index.) The lowest post-reclassified wage index assigned to a hospital in an all-urban State having a range of such values then is increased by this factor, the result of which establishes the State's alternative imputed floor. We amended § 412.64(h)(4) of the regulations to add new paragraphs to incorporate the finalized alternative methodology, and to make reference and date changes. In summary, for the FY 2013 wage index, we did not make any changes to the original imputed floor methodology at § 412.64(h)(4) and, therefore, made no changes to the New Jersey imputed floor computation for FY 2013. Instead, for FY 2013, we adopted a second, alternative methodology for use in cases where an all-urban State has a range of wage indexes assigned to its hospitals, but the State cannot benefit under the original methodology.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50589 through 50590), we extended the imputed floor policy (both the original methodology and the alternative methodology) for 1 additional year, through September 30, 2014, while we continued to explore potential wage index reforms.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49969 through 49970), for FY 2015, we adopted a policy to extend the imputed floor policy (both the original methodology and alternative methodology) for another year, through September 30, 2015, as we continued to explore potential wage index reforms. In that final rule, we revised the regulations at § 412.64(h)(4) and (h)(4)(vi) to reflect the 1-year extension of the imputed floor.

As discussed in section III.B. of the preamble of that FY 2015 final rule, we adopted the new OMB labor market area delineations beginning in FY 2015. Under the new OMB delineations, Delaware became an all-urban State, along with New Jersey and Rhode Island. Under the new OMB delineations, Delaware has three CBSAs, New Jersey has seven CBSAs, and Rhode Island continues to have only one CBSA (Providence-Warwick, RI-MA). We refer readers to a detailed discussion of our adoption of the new OMB labor market area delineations in section III.B. of the preamble of the FY 2015 IPPS/LTCH PPS final rule. Therefore, under the adopted new OMB delineations discussed in section III.B. of the preamble of the FY 2015 IPPS/LTCH PPS final rule, Delaware became an all-urban State and was subject to an imputed floor as well for FY 2015.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49497 through 49498), for FY 2016, we extended the imputed floor policy (under both the original methodology and the alternative methodology) for 1 additional year, through September 30, 2016. In that final rule, we revised the regulations at § 412.64(h)(4) and (h)(4)(vi) to reflect this additional 1-year extension.

For FY 2017, we are proposing to extend the imputed floor policy (under both the original methodology and the alternative methodology) for 1 additional year, through September 30, 2017, while we continue to explore potential wage index reforms. We are proposing to revise the regulations at § 412.64(h)(4) and (h)(4)(vi) to reflect this proposed additional 1-year extension. We are inviting public comments on the proposed additional 1-year extension of the imputed floor through September 30, 2017. The wage index and impact tables associated with this FY 2017 IPPS/LTCH PPS proposed rule (which are available on the Internet via the CMS Web site) reflect the proposed continued application of the imputed floor policy at § 412.64(h)(4) and a proposed national budget neutrality adjustment for the imputed floor for FY 2017. There are 20 providers in New Jersey that would receive an increase in their proposed FY 2017 wage index due to the proposed continued application of the imputed floor policy under the original methodology, and 10 hospitals in Rhode Island that would benefit under the alternative methodology. No providers in Delaware would benefit under the original methodology or the alternative methodology.

3. Proposed State Frontier Floor for FY 2017

Section 10324 of Public Law 111–148 requires that hospitals in frontier States cannot be assigned a wage index of less than 1.0000 (we refer readers to regulations at 42 CFR 412.64(m) and to a discussion of the implementation of this provision in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 through 50161)). Fifty hospitals would receive the frontier floor value of 1.0000 for their FY 2017 wage index in this proposed rule. These hospitals are located in Montana, Nevada, North Dakota, South Dakota, and Wyoming.

We are not proposing any changes to the frontier floor policy for FY 2017.

The areas affected by the proposed rural, imputed, and frontier floor policies for the proposed FY 2017 wage index are identified in Table 2 associated with this proposed rule, which is available via the Internet on the CMS Web site.

I. Proposed FY 2017 Wage Index Tables

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49498 and 49807 through 49808), we finalized a proposal to streamline and consolidate the wage index tables associated with the IPPS proposed and final rules for FY 2016 and subsequent fiscal years. Prior to FY 2016, the wage index tables had consisted of 12 tables (Tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4E, 4F, 4J, 9A, and 9C) that were made available via the Internet on the CMS Web site. Effective beginning FY 2016, with the exception of Table 4E, we streamlined and consolidated 11 tables (Tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4F, 4J, 9A, and 9C) into 2 tables (Tables 2 and 3). We refer readers to section VI. of the Addendum to this proposed rule for a discussion of the proposed wage index tables for FY 2017.

J. Proposed Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications

1. General Policies and Effects of Reclassification and Redesignation

Under section 1886(d)(10) of the Act, the Medicare Geographic Classification Review Board (MGCRB) considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. Hospitals must apply to the MGCRB to reclassify not later than 13 months prior to the start of the fiscal year for which reclassification is sought (usually by September 1). Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and must demonstrate characteristics similar to hospitals located in that area. The MGCRB issues its decisions by the end of February for reclassifications that become effective for the following fiscal year (beginning October 1). The regulations applicable to reclassifications by the MGCRB are located in 42 CFR 412.230 through 412.280. (We refer readers to a discussion in the FY 2002 IPPS final rule (66 FR 39874 and 39875) regarding how the MGCRB defines mileage for purposes of the proximity requirements.) The general policies for reclassifications and redesignations that we are proposing for FY 2017, and the policies for the effects of hospitals' reclassifications and redesignations on the wage index, are the same as those discussed in the FY 2012 IPPS/LTCH PPS final rule for the FY 2012 final wage index (76 FR 51595 and 51596). In addition, in the FY 2012 IPPS/LTCH PPS final rule, we discussed the effects on the wage index of urban hospitals reclassifying to rural areas under 42 CFR 412.103. Hospitals that are geographically located in States without any rural areas are ineligible to apply for rural reclassification in accordance with the provisions of 42 CFR 412.103.

2. MGCRB Reclassification and Redesignation Issues for FY 2017

a. FY 2017 Reclassification Requirements and Approvals

Under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. The specific procedures and rules that apply to the geographic reclassification process are outlined in regulations under 42 CFR 412.230 through 412.280.

At the time this proposed rule was constructed, the MGCRB had completed its review of FY 2017 reclassification requests. Based on such reviews, there are 299 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2017. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2017, hospitals reclassified beginning in FY 2015 or FY 2016 are eligible to continue to be reclassified to a particular labor market area based on such prior reclassifications for the remainder of their 3-year period. There were 302 hospitals approved for wage index reclassifications in FY 2015 that will continue for FY 2017, and 266 hospitals approved for wage index reclassifications in FY 2016 that will continue for FY 2017. Of all the hospitals approved for reclassification for FY 2015, FY 2016, and FY 2017, based upon the review at the time of this proposed rule, 867 hospitals are in a reclassification status for FY 2017.

Under the regulations at 42 CFR 412.273, hospitals that have been reclassified by the MGCRB are permitted to withdraw their applications within 45 days of the publication of a proposed rule. For information about withdrawing, terminating, or canceling a previous withdrawal or termination of a 3-year reclassification for wage index purposes, we refer readers to 42 CFR 412.273, as well as the FY 2002 IPPS final rule (66 FR 39887 through 39888) and the FY 2003 IPPS final rule (67 FR 50065 through 50066). Additional discussion on withdrawals and terminations, and clarifications regarding reinstating reclassifications and "fallback" reclassifications, were included in the FY 2008 IPPS final rule (72 FR 47333).

Changes to the wage index that result from withdrawals of requests for reclassification, terminations, wage index corrections, appeals, and the Administrator's review process for FY 2017 will be incorporated into the wage index values published in the FY 2017 IPPS/LTCH PPS final rule. These changes affect not only the wage index value for specific geographic areas, but also the wage index value that redesignated/reclassified hospitals receive; that is, whether they receive the wage index that includes the data for both the hospitals already in the area and the redesignated/reclassified hospitals. Further, the wage index value for the area from which the hospitals are redesignated/reclassified may be affected.

b. Requirements for FY 2018 Applications and Proposed Revisions Regarding Paper Application Requirements

Applications for FY 2018 reclassifications are due to the MGCRB by September 1, 2016 (the first working day of September 2016). We note that this is also the deadline for canceling a previous wage index reclassification withdrawal or termination under 42 CFR 412.273(d). Applications and other information about MGCRB reclassifications may be obtained, beginning in mid-July 2016, via the Internet on the CMS Web site at *https://www.cms.gov/Regulations-and-Guidance/Review-Boards/MGCRB/index.html*, or by calling the MGCRB at (410) 786–1174. The mailing address of the MGCRB is: 2520 Lord Baltimore Drive, Suite L, Baltimore, MD 21244–2670.

Under existing regulations at 42 CFR 412.256(a)(1), applications for reclassification must be mailed or delivered to the MGCRB, with a copy to CMS, and may not be submitted through the facsimile (FAX) process or by other electronic means. While existing regulations exclusively require paper applications, we believe this policy to be outdated and overly restrictive. Therefore, to promote ease of application for FY 2018 and subsequent years, we are proposing to revise this policy to require applications and supporting documentation to be submitted via the method prescribed in instructions by the MGCRB, with an electronic copy to CMS. Therefore, we are proposing to revise § 412.256(a)(1) to specify that an application must be submitted to the MGCRB according to the method prescribed by the MGCRB, with an electronic copy of the application sent to CMS. We are specifying that CMS copies should be sent via email to *wageindex@cms.hhs.gov*. We are inviting public comments on this proposal.

c. Other Policy Regarding Reclassifications for Terminated Hospitals

Under longstanding CMS policy, if a hospital that has an approved reclassification by the MGCRB terminates its CMS certification number (CCN), we terminate the reclassification status for that hospital when calculating the wage index, because the CCN is no longer active, and because the MGCRB makes its reclassification decisions based on CCNs. We believe this policy results in more accurate reclassifications when compiling CBSA labor market wage data, as it is often the case that hospitals that have terminated their CCNs have also terminated operations, and can no longer make timely and informed decisions regarding reclassification statuses, which could have ramifications for various wage index floors and labor market values.

However, as discussed in response to a comment in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49499 through 49500), in the case of a merger or acquisition where the acquiring hospital accepted the Medicare provider agreement of the acquired hospital located in a different market area that has an existing MGCRB reclassification, we do believe that the acquiring hospital should be able to make determinations regarding the reclassification status of the subordinate campus. While the original CCN for the acquired hospital would be considered terminated or "tied out" by CMS, in the specific situations where a hospital merges with or acquires another hospital located in a different labor market area to create a "multicampus" hospital and accepts the Medicare provider agreement of the acquired hospital, the reclassification status of the subordinate campus remains in effect. The acquired campus (that is, the hospital whose CCN is no longer active) may continue to receive its previously approved reclassification status, and the acquiring hospital is authorized to make timely requests to terminate, withdraw, or reinstate any reclassification for the subordinate campus for any remaining years of the reclassification. We believe this policy is consistent with existing regulations regarding reclassification status of "multicampus" hospitals at § 412.230(d)(2)(v). Hospitals should take care to review their status on Table 2 associated with this proposed rule (which is available via the Internet on the CMS Web site) and notify CMS if they believe a reclassification for a hospital was mistakenly terminated by CMS.

3. Redesignation of Hospitals Under Section 1886(d)(8)(B) of the Act

Section 1886(d)(8)(B)(i) of the Act requires the Secretary to treat a hospital located in a rural county adjacent to one or more urban areas as being located in the urban MSA to which the greatest number of workers in the county commute if certain adjacency and commuting criteria are met. The criteria utilize standards for designating MSAs published in the **Federal Register** by the Director of the Office of Management and Budget (OMB) based on the most recently available decennial population data. Effective beginning FY 2015, we use the OMB delineations based on the 2010 Decennial Census data to identify counties in which hospitals qualify under section 1886(d)(8)(B) of the Act to receive the wage index of the urban area. Hospitals located in these counties are referred to as "Lugar" hospitals and the counties themselves are often referred to as "Lugar" counties. The chart for this FY 2017 proposed rule with the listing of the rural counties containing the hospitals designated as urban under section 1886(d)(8)(B) of the Act is available via the Internet on the CMS Web site.

In an interim final rule with comment period (IFC) (CMS–1664–IFC) that appeared elsewhere in this issue of the **Federal Register**, CMS made regulatory changes in order to implement the decisions in *Geisinger Community Medical Center* v. *Secretary, United States Department of Health and Human Services,* 794 F.3d 383 (3d Cir. 2015) and *Lawrence + Memorial Hospital* v. *Burwell,* No. 15–164, 2016 WL 423702 (2d Cir. Feb. 4, 2015) in a nationally consistent manner. Specifically, the IFC revises the regulations at § 412.230(a)(5)(ii) and removes the regulatory provision at § 412.230(a)(5)(iii) to allow hospitals nationwide to reclassify based on their acquired rural status, effective with reclassifications beginning with FY 2018. The IFC also gives hospitals with an existing MGCRB reclassification the opportunity to seek rural reclassification for IPPS payment and other purposes under § 412.103 and keep their existing MGCRB reclassification.

As a consequence of the regulatory changes in the IFC that allow a hospital to have more than one reclassification simultaneously, we are clarifying in this proposed rule that a hospital with Lugar status may simultaneously receive an urban to rural reclassification under § 412.103. The IFC provides that when there is both a § 412.103 reclassification and an MGCRB reclassification, the MGCRB reclassification controls for wage index calculation and payment purposes (the IFC can be downloaded from the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/IPPS-Regulations-and-Notices.html*). Similarly, in this proposed rule, we are clarifying that we are treating the wage data of hospitals with simultaneous Lugar status and § 412.103 reclassification as Lugar for wage index calculation and wage index payment purposes. We believe it is appropriate to apply a similar policy for simultaneous MGCRB reclassification and § 412.103 reclassifications, and simultaneous Lugar and § 412.103 reclassifications, because CMS treats Lugar status as a reclassification for purposes of calculating the wage index in accordance with section 1886(d)(8)(C)(iii) of the Act. (Section 1886(d)(8)(C)(iii) of the Act states that the application of section 1886(d)(8)(B) of the Act or a decision of the MGCRB or the Secretary under section 1886(d)(10) of the Act may not result in the reduction of any county's wage index to a level below the wage index for rural areas in the State in which the county is located.) The wage index associated with the Lugar status, and not the wage index associated with the § 412.103 reclassification, is reflected accordingly in Table 2 associated with this proposed rule (which is available via the Internet on the CMS Web site). We note that, for payment purposes other than the wage index, a hospital with simultaneous § 412.103 status and Lugar reclassification receives payment as a rural hospital.

4. Waiving Lugar Redesignation for the Out-Migration Adjustment

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600), we adopted the policy that, beginning with FY 2012, an eligible hospital that waives its Lugar status in order to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS, including being considered rural for the DSH payment adjustment, effective for the fiscal year in which the hospital receives the out-migration adjustment. (We refer readers to a discussion of DSH payment adjustment under section IV.F. of the preamble of this proposed rule.)

In addition, we adopted a minor procedural change in that rule that allows a Lugar hospital that qualifies for and accepts the out-migration adjustment (through written notification to CMS within 45 days from the publication of the proposed rule) to waive its urban status for the full 3-year period for which its out-migration adjustment is effective. By doing so, such a Lugar hospital would no longer be required during the second and third years of eligibility for the out-migration adjustment to advise us annually that it prefers to continue being treated as rural and receive the out-migration adjustment. Therefore, under the procedural change, a Lugar hospital that requests to waive its urban status in order to receive the rural wage index in addition to the out-migration adjustment would be deemed to have accepted the out-migration adjustment and agrees to be treated as rural for the duration of its 3-year eligibility period, unless, prior to its second or third year of eligibility, the hospital explicitly notifies CMS in writing, within the required period (generally 45 days from the publication of the proposed rule), that it instead elects to return to its deemed urban status and no longer wishes to accept the out-migration adjustment. If the hospital does notify CMS that it is electing to return to its deemed urban status, it would again be treated as urban for all IPPS payment purposes.

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600) for a detailed discussion of the policy and process for waiving Lugar status for the out-migration adjustment.

K. Proposed Out-Migration Adjustment Based on Commuting Patterns of Hospital Employees for FY 2017

In accordance with section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, beginning with FY 2005, we established a process to make adjustments to the hospital wage index based on commuting patterns of hospital employees (the "out-migration" adjustment). The process, outlined in the FY 2005 IPPS final rule (69 FR 49061), provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county (or counties) with a higher wage index.

Section 1886(d)(13)(B) of the Act requires the Secretary to use data the Secretary determines to be appropriate to establish the qualifying counties. When the provision of section 1886(d)(13) of the Act was implemented for the FY 2005 wage index, we analyzed commuting data compiled by the U.S. Census Bureau that were derived from a special tabulation of the 2000 Census journey-to-work data for all industries (CMS extracted data applicable to hospitals). These data were compiled from responses to the "long-form" survey, which the Census Bureau used at the time and which contained questions on where residents in each county worked (69 FR 49062). However, the 2010 Census was "short form" only; information on where residents in each county worked was not collected as part of the 2010 Census. The Census Bureau worked with CMS to provide an alternative dataset based on the latest available data on where residents in each county worked in 2010, for use in developing a new out-migration adjustment based on new commuting patterns developed from the 2010 Census data beginning with FY 2016.

To determine the out-migration adjustments and applicable counties for FY 2016, we analyzed commuting data compiled by the Census Bureau that were derived from a custom tabulation of the American Community Survey (ACS), an official Census Bureau survey, utilizing 2008 through 2012 (5-Year) Microdata. The data were compiled from responses to the ACS questions regarding the county where workers reside and the county to which workers commute. As we discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49501), the same policies, procedures, and computation that were used for the FY 2012 out-migration adjustment were applicable for FY 2016, and we are proposing to use them again for FY 2017. We have applied the same policies, procedures, and computations since FY 2012, and we believe they continue to be appropriate for FY 2017. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49500 through 49502) for a full explanation of the revised data source.

For FY 2017, until such time that CMS finalizes out-migration adjustments based on the next Census, the out-migration adjustment continues to be based on the data derived from the custom tabulation of the ACS utilizing 2008 through 2012 (5-Year) Microdata. For FY 2017, we are not proposing any changes to the methodology or data source that we used for FY 2016. (We refer readers to a full discussion of the out-migration adjustment, including rules on deeming hospitals reclassified under section 1886(d)(8) or section 1886(d)(10) of the Act to have waived the out-migration adjustment, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51601 through 51602).) Table 2 associated with this proposed rule (which is available via the Internet on the CMS Web site) includes the proposed out-migration adjustments for the FY 2017 wage index.

L. Notification Regarding Proposed CMS "Lock-In" Date for Urban to Rural Reclassifications Under § 412.103

Under section 1886(d)(8)(E) of the Act, a qualifying prospective payment hospital located in an urban area may apply for rural status for payment purposes separate from reclassification through the MGCRB. Specifically, section 1886(d)(8)(E) of the Act provides that, not later than 60 days after the receipt of an application (in a form and manner determined by the Secretary) from a subsection (d) hospital that satisfies certain criteria, the Secretary shall treat the hospital as being located in the rural area (as defined in paragraph (2)(D)) of the State in which the hospital is located. We refer readers to the regulations at 42 CFR 412.103 for the general criteria and application requirements for a subsection (d) hospital to reclassify from urban to rural status in accordance with section 1886(d)(8)(E) of the Act. The FY 2012 IPPS/LTCH PPS final rule (76 FR 51595 through 51596) includes our policies regarding the effect of wage data from reclassified or redesignated hospitals.

Hospitals must meet the criteria to be reclassified from urban to rural status under § 412.103, as well as fulfill the requirements for the application process. However, under existing § 412.103(b), there is no timeframe requirement as to when hospitals must apply for the urban to rural reclassification. Therefore, a hospital can apply for the urban to rural reclassification at any time, and under § 412.103(d), the effective date of the hospital's rural status, once approved, is the filing date of the application.

There may be one or more reasons that a hospital applies for the urban to rural reclassification, and the timeframe that a hospital submits an application is often dependent on those reason(s). Because there are no timeframes for when a hospital must submit its application under § 412.103, it is the hospital's prerogative as to when it files the application with the CMS Regional Office. Because the wage index is part of the methodology for determining the prospective payments to hospitals for each fiscal year, we believe there should be a definitive timeframe within which a hospital should apply for rural status in order for the reclassification to be reflected in the next Federal fiscal year's wage data used for setting payment rates. As hospitals are aware, the IPPS ratesetting process that CMS undergoes each proposed and final rulemaking is complex and labor-intensive, and subject to a compressed timeframe in order to issue the final rule each year within the timeframes for publication. Accordingly, CMS must ensure that it receives, in a timely fashion, the necessary data, including, but not limited to, the list of hospitals that are reclassified from urban to rural status under § 412.103, in order to calculate the wage indexes and other IPPS rates.

Therefore, in this proposed rule, we are proposing a date by when we would "lock in" the list of hospitals that are reclassified from urban to rural status under § 412.103 in order to include them in the upcoming Federal fiscal year's wage index calculation provided for at § 412.64(h) and budget neutrality calculations provided for at

§§ 412.64(e)(1)(ii), (e)(2), and (e)(4) that are part of the ratesetting process). The ratesetting process is described in the Addendum of the annual proposed and final rules and includes the budget neutrality adjustments in accordance with the regulations at §§ 412.64(e)(1)(ii), (e)(2), and (e)(4), as well as adjustments for differences in area wage levels provided for at § 412.64(h). We believe that this proposal would introduce additional transparency and predictability regarding the timing of accounting for urban or rural status in the IPPS ratesetting each Federal fiscal year. We are proposing that this date for "locking in" the list of hospitals with rural status achieved under § 412.103 would be the second Monday in June of each year. Therefore, if a hospital is applying for an urban to rural reclassification under § 412.103 for the purpose and expectation that its rural status be reflected in the wage index and budget neutrality calculations for setting payment rates for the next Federal fiscal year, the hospital would need to file its application with the CMS Regional Office not later than 70 days prior to the second Monday in June. Because, under 412.103(c), the CMS Regional Office must notify the hospital of its approval or disapproval of the application within 60 days of the hospital's filing date (the date it is received by the CMS Regional Office, in accordance with § 412.103(b)(5)), we would expect that the extra 10 days would provide the CMS Regional Office with sufficient processing and administrative time to notify the CMS Central Office of the reclassification status of the applications by the second Monday in June of each year. This is the latest date that CMS would need the information in order to ensure that reclassified hospitals would be included as such in the wage index and budget neutrality calculations for setting payment rates for the next Federal fiscal year. This does not preclude a hospital from applying for reclassification under § 412.103 earlier or later than the proposed deadline. Nor does the proposed deadline change the fact that the rural reclassification is effective as of its filing date, in accordance with § 412.103(d). However, in order to ensure that a reclassification is reflected in the wage index and budget neutrality calculations for setting payment rates for the next Federal fiscal year, applications must be received by the CMS Regional Office (the filing date) by no later than 70 days prior to the second Monday in June of each year. If the CMS Central Office is informed of a reclassification status after the second Monday in June, for wage index and budget neutrality purposes, the reclassification would not be reflected in the payment rates until the following Federal fiscal year; that is, the Federal fiscal year following the next Federal fiscal year. We are proposing to revise § 412.103(b) by adding a new paragraph (6) to incorporate this proposed policy. Proposed § 412.103(b)(6) would specify that in order for a hospital to be treated as rural in the wage index and budget neutrality calculations under §§ 412.64(e)(1)(ii), (e)(2), (e)(4), and (h) for payment rates for the next Federal fiscal year, the hospital's filing date must be no later than 70 days prior to the second Monday in June of the current Federal fiscal year and the application must be approved by the CMS Regional Office in accordance with the requirements of § 412.103.

M. Process for Requests for Wage Index Data Corrections

The preliminary, unaudited Worksheet S–3 wage data files for the proposed FY 2017 wage index were made available on May 15, 2015, and the preliminary CY 2013 occupational mix data files on May 15, 2015, through the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2017-Wage-Index-Home-Page.html.*

On January 29, 2016, we posted a public use file (PUF) at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2017-Wage-Index-Home-Page.html* containing FY 2017 wage index data available as of January 28, 2016. This PUF contains a tab with the Worksheet S–3 wage data (which includes Worksheet S–3, Parts II and III wage data from cost reporting periods beginning on or after October 1, 2012 through September 30, 2013; that is, FY 2013 wage data), a tab with the occupational mix data (which includes data from the CY 2013 occupational mix survey, Form CMS–10079), and new for FY 2017, a tab containing the Worksheet S–3 wage data of hospitals deleted from the January 29, 2016 wage data PUF and a tab containing the CY 2013 occupational mix data (if any) of the hospitals deleted from the January 29, 2016 wage data PUF. In a memorandum dated January 21, 2016, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the January 29, 2016 wage index data PUFs, and the process and timeframe for requesting revisions in accordance with the FY 2017 Wage Index Timetable.

In the interest of meeting the data needs of the public, beginning with the proposed FY 2009 wage index, we post an additional PUF on our Web site that reflects the actual data that are used in computing the proposed wage index. The release of this file does not alter the current wage index process or schedule. We notify the hospital community of the availability of these data as we do with the current public use wage data files through our Hospital Open Door Forum. We encourage hospitals to sign up for automatic notifications of information about hospital issues and about the dates of the Hospital Open Door Forums at the CMS Web site at: *http://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/index.html.*

In a memorandum dated April 30, 2015, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the wage index data files and the process and timeframe for requesting revisions (including the specific deadlines listed later in this section). We also instructed the MACs to advise hospitals that these data were also made available directly through their representative hospital organizations.

If a hospital wished to request a change to its data as shown in May 15, 2015 wage data files and May 15, 2015 occupational mix data files, the hospital was to submit corrections along with complete, detailed supporting documentation to its MAC by September 2, 2015. Hospitals were notified of this deadline and of all other deadlines and requirements, including the requirement to review and verify their data as posted in the preliminary wage index data files on the Internet, through the letters sent to them by their MACs.

November 4, 2015 was the date by when MACs notified State hospital associations regarding hospitals that failed to respond to issues raised during the desk reviews. The MACs notified the hospitals by mid-January 2016 of any changes to the wage index data as a result of the desk reviews and the resolution of the hospitals' revision requests. The MACs also submitted the revised data to CMS by January 22, 2016. CMS published the proposed wage index PUFs that included hospitals' revised wage index data on January 29, 2016. Hospitals had until February 16, 2016, to submit requests to the MACs for reconsideration of adjustments made by the MACs as a result of the desk review, and to correct errors due to CMS' or the MAC's mishandling of the wage index data. Hospitals also were required to submit sufficient documentation to support their requests.

After reviewing requested changes submitted by hospitals, MACs were required to transmit to CMS any additional revisions resulting from the hospitals' reconsideration requests by March 24, 2016. The deadline for a hospital to request CMS intervention in cases where a hospital disagreed with a MAC's policy interpretation was April 5, 2016. We note that, as we did for the FY 2016 wage index, for the FY 2017 wage index, in accordance with the FY 2017 wage index timeline posted on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2017-Wage-Index-Home-Page.html*, the April appeals have to be sent via mail and email. We refer readers to the wage index timeline for complete details.

Hospitals are given the opportunity to examine Table 2, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2017-Wage-Index-Home-Page.html*. Table 2 contains each hospital's proposed adjusted average hourly wage used to construct the wage index values for the past 3 years, including the FY 2013 data used to construct the proposed FY 2017 wage index. We note that the proposed hospital average hourly wages shown in Table 2 only reflect changes made to a hospital's data that were transmitted to CMS by late February 2016.

We plan to post the final wage index data PUFs in late April 2016 on the Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2017-Wage-Index-Home-Page.html*. The April 2016 PUFs are made available solely for the limited purpose of identifying any potential errors made by CMS or the MAC in the entry of the final wage index data that resulted from the correction process previously described (revisions submitted to CMS by the MACs by March 24, 2016).

After the release of the April 2016 wage index data PUFs, changes to the wage and occupational mix data can only be made in those very limited situations involving an error by the MAC or CMS that the hospital could not have known about before its review of the final wage index data files. Specifically, neither the MAC nor CMS will approve the following types of requests:

- Requests for wage index data corrections that were submitted too late to be included in the data transmitted to CMS by the MACs on or before March 24, 2016.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the January 29, 2016 wage index PUFs.
- Requests to revisit factual determinations or policy interpretations made by the MAC or CMS during the wage index data correction process.

If, after reviewing the April 2016 final wage index data PUFs, a hospital believes that its wage or occupational mix data were incorrect due to a MAC or CMS error in the entry or tabulation of the final data, the hospital is given the opportunity to notify both its MAC and CMS regarding why the hospital believes an error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error). The hospital is required to send its request to CMS and to the MAC no later than May 23, 2016. Similar to the April appeals, beginning with the FY 2015 wage index, in accordance with the FY 2017 wage index timeline posted on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2017-Wage-Index-Home.html*, the May appeals must be sent via mail and email to CMS and the MACs. We refer readers to the wage index timeline for complete details.

Verified corrections to the wage index data received timely by CMS and the MACs (that is, by May 23, 2016) will be incorporated into the final FY 2017 wage index, which will be effective October 1, 2016.

We created the processes previously described to resolve all substantive wage index data correction disputes before we finalize the wage and occupational mix data for the FY 2017 payment rates. Accordingly, hospitals that do not meet the procedural deadlines set forth above will not be afforded a later opportunity to submit wage index data corrections or to dispute the MAC's decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines set forth above will not be permitted to challenge later, before the PRRB, the failure of CMS to make a requested data revision. We refer readers also to the FY 2000 IPPS final rule (64 FR 41513) for a discussion of the parameters for appeals to the PRRB for wage index data corrections.

Again, we believe the wage index data correction process described earlier provides hospitals with sufficient opportunity to bring errors in their wage and occupational mix data to the MAC's attention. Moreover, because hospitals have access to the final wage index data PUFs by late April 2016, they have the opportunity to detect any data entry or tabulation errors made by the MAC or CMS before the development and publication of the final FY 2017 wage index by August 2016, and the implementation of the FY 2017 wage index on October 1, 2016. Given these processes, the wage index implemented on October 1 should be accurate. Nevertheless, in the event that errors are identified by hospitals and brought to our attention after May 23, 2016, we retain the right to make midyear changes to the wage index under very limited circumstances.

Specifically, in accordance with 42 CFR 412.64(k)(1) of our regulations, we make midyear corrections to the wage index for an area only if a hospital can show that: (1) The MAC or CMS made an error in tabulating its data; and (2) the requesting hospital could not have known about the error or did not have an opportunity to correct the error, before the beginning of the fiscal year. For purposes of this provision, "before the beginning of the fiscal year" means by the May deadline for making corrections to the wage data for the following fiscal year's wage index (for example, May 23, 2016 for the FY 2017 wage index). This provision is not available to a hospital seeking to revise another hospital's data that may be affecting the requesting hospital's wage index for the labor market area. As indicated earlier, because CMS makes the wage index data available to hospitals on the CMS Web site prior to publishing both the proposed and final IPPS rules, and the MACs notify hospitals directly of any wage index data changes after completing their desk reviews, we do not expect that midyear corrections will be necessary. However, under our current policy, if the correction of a data error changes the wage index value for an area, the revised wage index value will be effective prospectively from the date the correction is made.

In the FY 2006 IPPS final rule (70 FR 47385 through 47387 and 47485), we revised 42 CFR 412.64(k)(2) to specify that, effective on October 1, 2005, that is, beginning with the FY 2006 wage index, a change to the wage index can be made retroactive to the beginning of the Federal fiscal year only when CMS determines all of the following: (1) The MAC or CMS made an error in tabulating data used for the wage index calculation; (2) the hospital knew about the error and requested that the MAC and CMS correct the error using the established process and within the established schedule for requesting corrections to the wage index data, before the beginning of the fiscal year for the applicable IPPS update (that is, by the May 23, 2016 deadline for the FY 2017 wage index); and (3) CMS agreed before October 1 that the MAC or CMS made an error in tabulating the hospital's wage index data and the wage index should be corrected.

In those circumstances where a hospital requested a correction to its wage index data before CMS calculated the final wage index (that is, by the May 23, 2016 deadline for the FY 2017 wage index), and CMS acknowledges that the error in the hospital's wage index data was caused by CMS' or the MAC's mishandling of the data, we believe that the hospital should not be penalized by our delay in publishing or implementing the correction. As with our current policy, we indicated that the provision is not available to a hospital seeking to revise another hospital's data. In addition, the provision cannot be used to correct prior years' wage index data; and it can only be used for the current Federal fiscal year. In situations where our policies would allow midyear corrections other than those specified in 42 CFR 412.64(k)(2)(ii), we continue to believe that it is appropriate to make prospective-only corrections to the wage index.

We note that, as with prospective changes to the wage index, the final retroactive correction will be made irrespective of whether the change increases or decreases a hospital's payment rate. In addition, we note that the policy of retroactive adjustment will still apply in those instances where a final judicial decision reverses a CMS denial of a hospital's wage index data revision request.

N. Proposed Labor Market Share for the Proposed FY 2017 Wage Index

Section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related and to adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the portion of hospital costs attributable to wages and wage-related costs as the labor-related share. The labor-related share of the prospective payment rate is adjusted by an index of relative labor costs, which is referred to as the wage index.

Section 403 of Public Law 108–173 amended section 1886(d)(3)(E) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless this would result in lower payments to a hospital than would otherwise be made. However, this provision of Public Law 108–173 did not change the legal requirement that the Secretary estimate from time to time the proportion of hospitals' costs that are attributable to wages and wage-related costs. Thus, hospitals receive payment based on either a 62-percent labor-related share, or the labor-related share estimated from time to time by the Secretary, depending on which labor-related share resulted in a higher payment.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50596 through 50607), we rebased and revised the hospital market basket. We established a FY 2010-based IPPS hospital market basket to replace the FY 2006-based IPPS hospital market basket, effective October 1, 2013. In that final rule, we presented our analysis and conclusions regarding the frequency and methodology for updating the labor-related share for FY 2014. Using the FY 2010-based IPPS market basket, we finalized a labor-related share for FY 2014, FY 2015, and FY 2016 of 69.6 percent. In addition, in FY 2014, we implemented this revised and rebased labor-related share in a budget neutral manner (78 FR 51016). However, consistent with section 1886(d)(3)(E) of the Act, we did not take into account the additional payments that would be made as a result of hospitals with a wage index less than or equal to 1.0000 being paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.0000.

The labor-related share is used to determine the proportion of the national IPPS base payment rate to which the area wage index is applied. In this proposed rule, for FY 2017, we are not proposing to make any further changes to the national average proportion of operating costs that are attributable to wages and salaries, employee benefits, contract labor, the labor-related portion of professional fees, administrative and facilities support services, and all other labor-related services. Therefore, for FY 2017, we are proposing to continue to use a labor-related share of 69.6 percent for discharges occurring on or after October 1, 2016.

As discussed in section IV.A of the preamble of this proposed rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we applied the Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage to the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need for us to calculate a Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage for application to the Puerto Rico-specific standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national labor-related share and nonlabor-related share percentages that are applied to the national standardized amount. Accordingly, for FY 2017, we are not proposing a Puerto Rico-specific labor-related share percentage or a nonlabor-related share percentage.

Tables 1A and 1B, which are published in section VI. of the Addendum to this FY 2017 IPPS/LTCH PPS proposed rule and available via the Internet on the CMS Web site, reflect the proposed national labor-related share, which is also applicable to Puerto Rico hospitals. For FY 2017, for all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are less than or equal to 1.0000, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are greater than 1.000, for FY 2017, we are proposing to apply the wage index to a proposed labor-related share of 69.6 percent of the national standardized amount.

O. Solicitation of Comments on Treatment of Overhead and Home Office Costs in the Wage Index Calculation

Section III.D. of the preamble of this proposed rule states that the method used to compute the proposed FY 2017 wage index without an occupational mix adjustment follows the same methodology that we used to compute the FY 2012, FY 2013, FY 2014, FY 2015, and FY 2016 final wage indexes without an occupational mix adjustment (76 FR 51591 through 51593, 77 FR 53366 through 53367, 78 FR 50587 through 50588, 79 FR 49967, and 80 FR 49491 through 49492, respectively).

As discussed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51592), in "Step 4" of the calculation of the unadjusted wage index, for each hospital reporting both total overhead salaries and total overhead hours greater than zero, we allocate overhead costs to areas of the hospital excluded from the wage index calculation. We also compute the amounts of overhead wage-related costs to be allocated to excluded areas. Finally, we subtract the computed overhead salaries, overhead wage-related costs, and hours associated with excluded areas from the total salaries (plus allowable wage-related costs) and hours derived in "Steps 2 and 3" of the calculation of the unadjusted wage index. (We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51592) for a description of the calculation of the unadjusted wage index.) We first began to remove from the wage index the overhead salaries and hours allocated to excluded areas beginning with the FY 1999 wage index calculation (63 FR 40971 and 40972). Beginning with the FY 2002 wage index calculation, we estimated and removed overhead wage-related costs allocated to excluded areas in addition to removing overhead salaries and hours allocated to excluded areas (66 FR 39863 and 39864). We began to estimate and remove overhead wage-related costs associated with excluded areas because we realized that without doing so, the formula resulted in large and inappropriate increases in the average hourly wages of some hospitals, particularly hospitals with large overhead and excluded area costs. These findings led us to believe that not all hospitals were fully or consistently allocating their overhead salaries among the lines on Worksheet S–3, Part II, of the hospital cost report for allowable wage-related costs (Worksheet S–3, Part II, lines 13 and 14 on CMS Form 2552–96, and lines 17 and 18 on CMS Form 2552–10), and nonallowable wage-related costs associated with excluded areas (Worksheet S–3, Part II, line 15 on CMS Form 2552–96 and line 19 on CMS Form 2552–10). Therefore, we determined that it was necessary to estimate and remove overhead wage-related costs allocated to excluded areas, and we have been doing so in "Step 4" of the unadjusted wage index calculation since FY 2002.

With the implementation of CMS Form 2552–10, Worksheet S–3, Part IV was added to the cost report on which hospitals are required to itemize their wage-related costs (formerly reported on Exhibit 6 of CMS Form-339). The total amount of wage-related costs reported on Worksheet S–3, Part II, lines 17 through 25 (CMS Form 2552–10) must correspond to the total core wage-related costs on Worksheet S–3, Part IV, line 24. (We refer readers to the instructions for line 17 of Worksheet S–3, Part II, which state: "Enter the core wage-related costs from Worksheet S–3, Part IV, line 24.") Hospitals report wage-related costs associated with excluded areas of the hospital on Worksheet S–3, Part II, line 19. We understand that hospitals use an allocation methodology to allocate total wage-related costs to each of lines Worksheet S–3, Part II, lines 17 through 25 respectively, typically based on the ratio of individual line costs to total wage-related costs on lines 17 through 25. Alternatively, we understand that hospitals use the ratio of full-time equivalent (FTE) hours of an individual line to total FTE hours for those lines 17 through 25. Because the wage-related costs of employees who work in overhead areas of the hospital are included in the wage-related costs of the hospital reported on Worksheet S–3, Part IV, and in turn, on Worksheet S–3, Part II, it is possible to conclude that hospitals' own allocation methodologies are properly allocating an accurate amount of wage-related costs for both direct cost centers and overhead areas to line 19 for the excluded areas. Accordingly, the question has been raised whether it continues to be necessary for CMS to estimate and remove the overhead wage-related costs associated with excluded areas from the unadjusted wage index calculation.

We have tested the effect on the average hourly wages of hospitals if we would not estimate and remove the overhead wage-related costs associated with excluded areas from the unadjusted wage index calculation. The results show that the problem manifested in the formula prior to FY 2002 continues to be a concern; that is, while the average hourly wages of all hospitals with excluded areas are impacted, hospitals that have particularly large excluded areas experience large and inappropriate increases to their average hourly wages. For example, one hospital with an excluded area percentage of 95 percent that has an average hourly wage of approximately $32 under our current methodology would have an average hourly wage of $128 under the formula in effect prior to FY 2002 (that is, *without* removal of overhead wage-related costs). Accordingly, we believe that, at this point, there is a need for CMS to continue to estimate and remove the overhead wage-related costs associated with excluded areas from the unadjusted wage index calculation. However, in an effort to improve consistency in hospital cost reporting practices and to improve the accuracy of the wage index, we are considering the possibility of future rulemaking or cost reporting changes, or a combination of both, where hospitals would apply a single allocation methodology between Worksheet S–3, Part IV and Worksheet S–3, Part II, lines 17 through 25. For example, one possibility is the modification and expansion of Worksheet S–3, Part IV to add columns that would correspond to each line 17 through 25 of Worksheet S–3, Part II. In addition, Worksheet S–3, Part IV could employ one or two standard statistical allocation methods, facilitating a direct flow of the allocated amounts to each line 17 through 25 of Worksheet S–3, Part II. We are soliciting comments from stakeholders to gain a better understanding of the nature of hospitals' reporting of wage-related costs on Worksheet S–3, Part IV, statistical allocation methods that hospitals typically use to allocate their wage-related costs, the treatment of direct versus overhead employee wage-related costs, and suggestions for possible modifications to Worksheet S–3, Parts II and IV respectively, which would preempt the need for CMS to estimate and remove overhead wage-related costs associated with excluded areas from the unadjusted wage index.

Another issue about which we are concerned and would like to solicit public comments relates to inconsistent reporting of home office salaries and wage-related costs. Worksheet S–2, Part I, line 140, requires hospitals to complete Worksheet A–8–1 if they have any related organization or home office costs claimed as defined in the Provider Reimbursement Manual, CMS Pub. 15–1, Chapter 10, Section 1002, and 42 CFR 413.17. Then, line 14 of Worksheet S–3, Part II instructs hospitals to enter the salaries and wage-related costs paid to personnel who are affiliated with a home office and/or related organization, who provide services to the hospital, and whose salaries are *not* included on Worksheet A, Column 1. Because home office salaries and wage-related costs are not included on Worksheet A, Column 1, we are concerned that hospitals are not including home office costs on Worksheet A, Column 2 or Column 6 in the appropriate cost centers on lines 4 through 17, adjusted from Worksheet A–8 or Worksheet A–8–1.[20] Another concern is a hospital's inadvertent inclusion on line 14 of the home office salaries or wage-related costs associated with excluded areas on Worksheet S–3, Part II, lines 9 or 10. In addition, we are concerned about the amalgam of personnel costs that hospitals report on line 14, particularly when another more precise line exists for those personnel costs to be reported. For example, if cafeteria services are provided through the home office, those wages and hours should not be reported on line 14, but instead should be reported on the more specific cost center for Cafeteria, Worksheet S–3, Part II, line 36 (corresponding to Cafeteria on Worksheet A, line 11[21]). We note that, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967), we reiterated our requirement that all hospitals must document salaries, wages, and hours for the purpose of reporting this information on Worksheet S–3, Part II, lines 32, 33, 34, and/or 35 (for either directly employed housekeeping and dietary employees on lines 32 and 34, and contract labor on lines 33 and 35). We have learned of instances where housekeeping or dietary services are provided through the home office, and the hospital reported those wages and hours on line 14. This is inconsistent with other hospitals' reporting of housekeeping and dietary services on lines 32 through 35. As stated in the FY 2015 IPPS/LTCH PPS final rule, we have instructed the MACs to impute housekeeping or dietary wages and hours when hospitals have not properly completed those lines 32 through 35. Hospitals whose housekeeping or dietary services (either direct or under contract) are provided through their home office are not exempt from this requirement to report wages and hours on the specific cost centers for housekeeping and dietary. Hospitals should also take care to report housekeeping and dietary services in the appropriate cost centers on Worksheet A, lines 9 and 10 respectively. Because the nature of services provided by home office personnel are for general management or administrative services related to the provision of patient care (CMS Pub. 15–1, Chapter 21, Section 2150), and may be provided to multiple areas of the hospital, we are considering ending reporting of home office costs on line 14 of Worksheet S–3, Part II, and instead we may require reporting of home office costs as part of the overhead lines, possibly by adding lines or columns, or subscripting existing line 27 (Administrative & General), and line 28 (Administrative & General for contract labor). We are soliciting public comments to gain a better understanding of hospitals' reporting of home office salaries and wage-related costs for possible future revisions to the cost report instructions and lines.

IV. Other Decisions and Changes to the IPPS for Operating Costs and Direct Graduate Medical Education (GME) and Indirect Medical Education (IME) Costs

A. Changes to Operating Payments for Subsection (d) Puerto Rico Hospitals as a Result of Section 601 of Public Law 114–113

Prior to January 1, 2016, Puerto Rico hospitals were paid with respect to operating costs of inpatient hospital services for inpatient hospital discharges based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. As a result of the amendment made by section 601 of Public Law 114–113, on February 4, 2016, we issued Change Request 9523 which updated the payment rates for subsection (d) Puerto Rico hospitals for discharges occurring on or after January 1, 2016. Change Request 9523 can be downloaded from the CMS Web site at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2016-Transmittals-Items/R3449CP.html.*

For operating costs for inpatient hospital discharges occurring in FY 2017 and subsequent fiscal years, consistent with the provisions of section 1886(d)(9)(E) of the Act as amended by section 601 of Public Law 114–113, subsection (d) Puerto Rico hospitals will continue to be paid based on 100 percent of the national standardized amount.

In this proposed rule, we are proposing to make conforming changes to the regulations at 42 CFR 412.204 to reflect the current law that is effective for discharges occurring on or after January 1, 2016. Specifically, we are proposing to add a new paragraph (e) to § 412.204 to reflect that, beginning January 1, 2016, subsection (d) Puerto Rico hospitals are paid based on 100 percent of the national standardized amount. We also are proposing to revise paragraph (d) of § 412.204 to specify that subsection (d) Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount for discharges occurring through December 31, 2015.

B. Proposed Changes in the Inpatient Hospital Update for FY 2017 (§ 412.64(d))

1. Proposed FY 2017 Inpatient Hospital Update

In accordance with section 1886(b)(3)(B)(i) of the Act, each year we update the national standardized amount for inpatient hospital operating costs by a factor called the "applicable percentage increase." For FY 2017, we are setting the applicable percentage increase by applying the adjustments listed in this section in the same sequence as we did for FY 2016. Specifically, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. The applicable percentage increase under the IPPS is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to—

(a) A reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act;

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[20] CMS Pub. 15–2, Chapter 40, Section 4013, Worksheet A instructions for column 6: "Enter on the appropriate lines in column 6 the amounts of any adjustments to expenses indicated on Worksheet A–8, column 2," and the note for line 12 of Worksheet A–8, section 4016: "Worksheet A–8–1 represents the detail of the various cost centers on Worksheet A which must be adjusted."

[21] CMS Pub. 15–2, Chapter 40, Section 4013, Worksheet A instructions under Line Descriptions: "The trial balance of expenses is broken down into general service, inpatient routine service, ancillary service, outpatient service, other reimbursable, special purpose, and nonreimbursable cost center categories *to facilitate the transfer of costs to the various worksheets. The line numbers on Worksheet A are used on subsequent worksheets.* * * *" (emphasis added).

(b) A reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act;

(c) An adjustment based on changes in economy-wide productivity (the multifactor productivity (MFP) adjustment); and

(d) An additional reduction of 0.75 percentage point as required by section 1886(b)(3)(B)(xii) of the Act.

Sections 1886(b)(3)(B)(xi) and (b)(3)(B)(xii) of the Act, as added by section 3401(a) of the Affordable Care Act, state that application of the MFP adjustment and the additional FY 2017 adjustment of 0.75 percentage point may result in the applicable percentage increase being less than zero.

We note that, in compliance with section 404 of the MMA, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50596 through 50607), we replaced the FY 2006-based IPPS operating and capital market baskets with the revised and rebased FY 2010-based IPPS operating and capital market baskets for FY 2014. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49993 through 49996) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49508 through 49511), we continued to use the FY 2010-based IPPS operating and capital market baskets for FY 2015 and FY 2016 and the labor-related share of 69.6 percent, which was based on the FY 2010-based IPPS market basket. For FY 2017, we are proposing to continue using the FY 2010-based IPPS operating and capital market baskets and the proposed labor-related share of 69.6 percent, which is based on the FY 2010-based IPPS market basket.

Based on the most recent data available for this FY 2017 proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we are proposing to base the proposed FY 2017 market basket update used to determine the applicable percentage increase for the IPPS on IHS Global Insight, Inc.'s (IGI's) first quarter 2016 forecast of the FY 2010-based IPPS market basket rate-of-increase with historical data through fourth quarter 2015, which is estimated to be 2.8 percent. We are proposing that if more recent data subsequently become available (for example, a more recent estimate of the market basket and the MFP adjustment), we would use such data, if appropriate, to determine the FY 2017 market basket update and the MFP adjustment in the final rule.

For FY 2017, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the standardized amount as specified in the table that appears later in this section.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the MFP adjustment. As we explained in that rule, section 1886(b)(3)(B)(xi)(II) of the Act, as added by section 3401(a) of the Affordable Care Act, defines this productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business MFP (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period). The Bureau of Labor Statistics (BLS) publishes the official measure of private nonfarm business MFP. We refer readers to the BLS Web site at *http://www.bls.gov/mfp* for the BLS historical published MFP data.

MFP is derived by subtracting the contribution of labor and capital input growth from output growth. The projections of the components of MFP are currently produced by IGI, a nationally recognized economic forecasting firm with which CMS contracts to forecast the components of the market baskets and MFP. As we discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49509), beginning with the FY 2016 rulemaking cycle, the MFP adjustment is calculated using the revised series developed by IGI to proxy the aggregate capital inputs. Specifically, in order to generate a forecast of MFP, IGI forecasts BLS aggregate capital inputs using a regression model. A complete description of the MFP projection methodology is available on the CMS Web site at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html*. As discussed in the FY 2016 IPPS/LTCH PPS final rule, if IGI makes changes to the MFP methodology, we will announce them on our Web site rather than in the annual rulemaking.

For FY 2017, we are proposing an MFP adjustment of 0.5 percentage point. Similar to the market basket update, for the proposed rule, we used the most recent data available to compute the MFP adjustment. As noted previously, we are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2017 market basket update and MFP adjustment for the final rule.

Based on the most recent data available for this proposed rule, as described previously, we have determined four proposed applicable percentage increases to the standardized amount for FY 2017, as specified in the following table:

PROPOSED FY 2017 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS

FY 2017	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Proposed Market Basket Rate-of-Increase	2.8	2.8	2.8	2.8
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.7	−0.7
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−2.1	0.0	−2.1
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.5	−0.5	−0.5	−0.5
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.75	−0.75	−0.75	−0.75

PROPOSED FY 2017 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS—Continued

FY 2017	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Proposed Applicable Percentage Increase Applied to Standardized Amount	1.55	−0.55	0.85	−1.25

We are proposing to revise the existing regulations at 42 CFR 412.64(d) to reflect the current law for the FY 2017 update. Specifically, in accordance with section 1886(b)(3)(B) of the Act, we are proposing to add a new paragraph (vii) to § 412.64(d)(1) to reflect the applicable percentage increase to the FY 2017 operating standardized amount as the percentage increase in the market basket index, subject to the reductions specified under § 412.64(d)(2) for a hospital that does not submit quality data and § 412.64(d)(3) for a hospital that is not a meaningful EHR user, less an MFP adjustment and less an additional reduction of 0.75 percentage point.

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital-specific rates for SCHs and MDHs also is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. We note that section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted on April 16, 2015) extended the MDH program (which, under previous law, was to be in effect for discharges on or before March 31, 2015 only) for discharges occurring on or after April 1, 2015, through FY 2017 (that is, for discharges occurring on or before September 30, 2017).

For FY 2017, we are proposing the following updates to the hospital-specific rates applicable to SCHs and MDHs: A proposed update of 1.55 percent for a hospital that submits quality data and is a meaningful EHR user; a proposed update of 0.85 percent for a hospital that fails to submit quality data and is a meaningful EHR user; a proposed update of −0.55 percent for a hospital that submits quality data and is not a meaningful EHR user; and a proposed update of −1.25 percent for a hospital that fails to submit quality data and is not a meaningful EHR user. As mentioned previously, for this FY 2017 proposed rule, we are using IGI's first quarter 2016 forecast of the FY 2010-based IPPS market basket update with historical data through fourth quarter 2015. Similarly, we are using IGI's first quarter 2016 forecast of the MFP adjustment. We are proposing that if more recent data subsequently become available (for example, a more recent estimate of the market basket increase and the MFP adjustment), we would use such data, if appropriate, to determine the update for SCHs and MDHs in the final rule.

2. Proposed FY 2017 Puerto Rico Hospital Update

As discussed in section IV.A. of the preamble of this proposed rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Section 601 of Public Law 114–113 amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount under the amendments to section 1886(d)(9)(E) of the Act, there is no longer a need for us to propose an update to the Puerto Rico standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the same update to the national standardized amount discussed under section IV.B.1. of the preamble of this proposed rule. Accordingly, for FY 2017, we are proposing an applicable percentage increase of 1.55 percent to the standardized amount for hospitals located in Puerto Rico.

We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for "subsection (d)" hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.

In addition, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016, and also to apply the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act to Puerto Rico hospitals that are not meaningful EHR users, effective FY 2022. Accordingly, because the provisions of section 1886(b)(3)(B)(ix) of the Act are not applicable to hospitals located in Puerto Rico until FY 2022, the adjustments under this provision are not applicable for FY 2017.

C. Rural Referral Centers (RRCs): Proposed Annual Updates to Case-Mix Index and Discharge Criteria (§ 412.96)

Under the authority of section 1886(d)(5)(C)(i) of the Act, the regulations at § 412.96 set forth the criteria that a hospital must meet in order to qualify under the IPPS as a rural referral center (RRC). RRCs receive some special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 402 of Public Law 108–173 raised the DSH payment adjustment for RRCs such that they are not subject to the 12-percent cap on DSH payments that is applicable to other rural hospitals. RRCs also are not subject to the proximity criteria when applying for geographic reclassification. In addition, they do not have to meet the requirement that a hospital's average hourly wage must exceed, by a certain percentage, the average hourly wage of the labor market area in which the hospital is located.

Section 4202(b) of Public Law 105–33 states, in part, that any hospital classified as an RRC by the Secretary for FY 1991 shall be classified as such an RRC for FY 1998 and each subsequent fiscal year. In the August 29, 1997 IPPS final rule with comment period (62 FR 45999), we reinstated RRC status for all hospitals that lost that status due to triennial review or MGCRB reclassification. However, we did not reinstate the status of hospitals that lost RRC status because they were now urban for all purposes because of the OMB designation of their geographic area as urban. Subsequently, in the August 1, 2000 IPPS final rule (65 FR 47089), we indicated that we were revisiting that decision. Specifically, we stated that we would permit hospitals that previously qualified as an RRC and lost their status due to OMB redesignation of the county in which they are located from rural to urban, to be reinstated as an RRC. Otherwise, a hospital seeking RRC status must satisfy all of the other applicable criteria. We use the definitions of "urban" and "rural" specified in Subpart D of 42 CFR part 412. One of the criteria under which a hospital may qualify as an RRC is to have 275 or more beds available for use (§ 412.96(b)(1)(ii)). A rural hospital that does not meet the bed size requirement can qualify as an RRC if the hospital meets two mandatory prerequisites (a minimum case-mix index (CMI) and a minimum number of discharges), and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume). (We refer readers to § 412.96(c)(1) through (c)(5) and the September 30, 1988 **Federal Register** (53 FR 38513) for additional discussion.) With respect to the two mandatory prerequisites, a hospital may be classified as an RRC if—

- The hospital's CMI is at least equal to the lower of the median CMI for urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median CMI for all urban hospitals nationally; and
- The hospital's number of discharges is at least 5,000 per year, or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located. The number of discharges criterion for an osteopathic hospital is at least 3,000 discharges per year, as specified in section 1886(d)(5)(C)(i) of the Act.

1. Case-Mix Index (CMI)

Section 412.96(c)(1) provides that CMS establish updated national and regional CMI values in each year's annual notice of prospective payment rates for purposes of determining RRC status. The methodology we used to determine the national and regional CMI values is set forth in the regulations at § 412.96(c)(1)(ii). The proposed national median CMI value for FY 2017 is based on the CMI values of all urban hospitals nationwide, and the proposed regional median CMI values for FY 2017 are based on the CMI values of all urban hospitals within each census region, excluding those hospitals with approved teaching programs (that is, those hospitals that train residents in an approved GME program as provided in § 413.75). These proposed values are based on discharges occurring during FY 2015 (October 1, 2014 through September 30, 2015), and include bills posted to CMS' records through December 2015.

We are proposing that, in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2016, they must have a CMI value for FY 2015 that is at least—

- 1.6125 (national—all urban); or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

The proposed CMI values by region are set forth in the following table.

Region	Case-mix index value
1. New England (CT, ME, MA, NH, RI, VT)	1.3637
2. Middle Atlantic (PA, NJ, NY)	1.4441
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.51235
4. East North Central (IL, IN, MI, OH, WI)	1.5324
5. East South Central (AL, KY, MS, TN)	1.45055
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.59535
7. West South Central (AR, LA, OK, TX)	1.643
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.6966
9. Pacific (AK, CA, HI, OR, WA)	1.616

We intend to update the preceding CMI values in the FY 2017 final rule to reflect the updated FY 2015 MedPAR file, which would contain data from additional bills received through March 2016.

A hospital seeking to qualify as an RRC should obtain its hospital-specific CMI value (not transfer-adjusted) from its MAC. Data are available on the Provider Statistical and Reimbursement (PS&R) System. In keeping with our policy on discharges, the CMI values are computed based on all Medicare patient discharges subject to the IPPS MS–DRG-based payment.

2. Discharges

Section 412.96(c)(2)(i) provides that CMS set forth the national and regional numbers of discharges criteria in each year's annual notice of prospective payment rates for purposes of determining RRC status. As specified in section 1886(d)(5)(C)(ii) of the Act, the national standard is set at 5,000 discharges. For FY 2017, we are proposing to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2014 (that is, October 1, 2013 through September 30, 2014), which are the latest cost report data available at the time this proposed rule was developed.

We are proposing that, in addition to meeting other criteria, a hospital, if it is to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2016, must have, as the number of discharges for its cost reporting period that began during FY 2014, at least—

- 5,000 (3,000 for an osteopathic hospital); or
- The median number of discharges for urban hospitals in the census region in which the hospital is located as indicated in the following table.

Region	Number of discharges
1. New England (CT, ME, MA, NH, RI, VT)	8,090
2. Middle Atlantic (PA, NJ, NY)	10,745
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	10,309
4. East North Central (IL, IN, MI, OH, WI)	8,090
5. East South Central (AL, KY, MS, TN)	7,457
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	7,718
7. West South Central (AR, LA, OK, TX)	5,027
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	8,621
9. Pacific (AK, CA, HI, OR, WA)	8,509

We intend to update these numbers in the FY 2017 final rule based on the latest available cost report data.

We note that the median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges. Therefore, under this proposed rule, 5,000 discharges is the minimum criterion for all hospitals, except for osteopathic hospitals for which the minimum criterion is 3,000 discharges.

D. Proposed Payment Adjustment for Low-Volume Hospitals (§ 412.101)

1. Background

Section 1886(d)(12) of the Act provides for an additional payment to each qualifying low-volume hospital that is paid under IPPS beginning in FY 2005, and the low-volume hospital payment policy is set forth in the regulations at 42 CFR 412.101. Sections 3125 and 10314 of the Affordable Care Act provided for a temporary change in the low-volume hospital payment policy for FYs 2011 and 2012. Specifically, the provisions of the Affordable Care Act amended the qualifying criteria for low-volume hospitals to specify, for FYs 2011 and 2012, that a hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 1,600 discharges of individuals entitled to, or enrolled for, benefits under Medicare Part A during the fiscal year. In addition, the statute as amended by the Affordable Care Act, provides that the low-volume hospital payment adjustment (that is, the percentage increase) is determined using a continuous linear sliding scale ranging from 25 percent for low-volume hospitals with 200 or fewer discharges of individuals entitled to, or enrolled for, benefits under Medicare Part A in the fiscal year to 0 percent for low-volume hospitals with greater than 1,600 discharges of such individuals in the fiscal year. We revised the regulations governing the low-volume hospital payment adjustment policy at § 412.101 to reflect the changes to the qualifying criteria and the calculation of the payment adjustment for low-volume hospitals according to the provisions of the Affordable Care Act in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414).

The temporary changes to the low-volume hospital qualifying criteria and the payment adjustment originally provided for by the Affordable Care Act have been extended by subsequent legislation as follows: Through FY 2013, by the American Taxpayer Relief Act of 2012 (ATRA), Public Law 112–240; through March 31, 2014, by the Pathway for SGR Reform Act of 2013, Public Law 113– 167; through March 31, 2015, by the Protecting Access to Medicare Act of 2014 (PAMA), Public Law 113–93; and most recently through FY 2017, by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Public Law 114–10. For additional details on the implementation of the previous extensions of the temporary changes to the low-volume hospital qualifying criteria and payment adjustment originally provided for by the Affordable Care Act, we refer readers to the following **Federal Register** documents: The FY 2013 IPPS notice (78 FR 14689 through 14691); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50611 through 50612); the FY 2014 IPPS interim final rule with comment period (79 FR 15022 through 15025); the FY 2014 IPPS notice (79 FR 34444 through 34446); the FY 2015 IPPS/LTCH PPS final rule (79 FR 49998 through 50001); and the FY 2016 IPPS interim final rule with comment period (80 FR 49594 through 49595).

2. Proposed Low-Volume Hospital Definition and Payment Adjustment for FY 2017

Under section 1886(d)(12) of the Act, as amended by section 204 of the MACRA, the temporary changes in the low-volume hospital payment policy originally provided by the Affordable Care Act and extended through subsequent legislation, are effective through FY 2017. In this proposed rule, consistent with our historical approach, we are proposing to update the discharge data source used to identify qualifying low-volume hospitals and calculate the payment adjustment (percentage increase) for FY 2017. Under § 412.101(b)(2)(ii), for the applicable fiscal years, a hospital's Medicare discharges from the most recently available MedPAR data, as determined by CMS, are used to determine if the hospital meets the discharge criteria to receive the low-volume payment adjustment in the current year and to determine the applicable low-volume percentage increase for qualifying hospitals. The applicable low-volume percentage increase for FY 2017 is determined using a continuous linear sliding scale equation that results in a low-volume hospital payment adjustment ranging from an additional 25 percent for hospitals with 200 or fewer Medicare discharges to a zero percent additional payment adjustment for hospitals with 1,600 or more Medicare discharges. For FY 2017, consistent with our historical policy, we are proposing that qualifying low-volume hospitals and their payment adjustment would be determined using the most recently available Medicare discharge data from the December 2015 update of the FY 2015 MedPAR file, as these data are the most recent data available. Table 14 listed in the Addendum of this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) lists the "subsection (d)" hospitals with fewer than 1,600 Medicare discharges based on the claims data from the December 2015 update of the FY 2015 MedPAR file and their potential proposed low-volume payment adjustment for FY 2017. Consistent with past practice, we note that this list of hospitals with fewer than 1,600 Medicare discharges in Table 14 does not reflect whether or not the hospital meets the mileage criterion. Eligibility for the low-volume hospital payment adjustment for FY 2017 also is dependent upon meeting the mileage criterion specified at § 412.101(b)(2)(ii); that is, the hospital must be located more than 15 road miles from any other IPPS hospital. In other words, eligibility for the low-volume hospital payment adjustment for FY 2017 also is dependent upon meeting (in the case of a hospital that did not qualify for the low-volume hospital payment adjustment in FY 2016) or continuing to meet (in the case of a hospital that did qualify for the low-volume hospital payment adjustment in FY 2016) the mileage criterion specified at § 412.101(b)(2)(ii). Consistent with historical practice, we are proposing that if more recent Medicare discharge data become available, we would use that updated data to determine qualifying low-volume hospitals and their payment adjustment in the final rule, and update Table 14 to reflect that updated data.

In order to receive a low-volume hospital payment adjustment under § 412.101 for FY 2017, consistent with our previously established procedure, we are proposing that a hospital must notify and provide documentation to its MAC that it meets the discharge and mileage criteria under § 412.101(b)(2)(ii). Specifically, for FY 2017, we are proposing that a hospital must make a written request for low-volume hospital status that is received by its MAC no later than September 1, 2016, in order for the applicable low-volume hospital payment adjustment to be applied to payments for its FY 2017 discharges occurring on or after October 1, 2016. Under this procedure, a hospital that qualified for the low-volume hospital payment adjustment in FY 2016 may continue to receive a low-volume hospital payment adjustment for FY 2017 without reapplying if it continues to meet the Medicare discharge criterion established for FY 2017 and the mileage criterion. However, the hospital must send written verification that is received by its MAC no later than September 1, 2016, stating that it continues to be located more than 15 miles from any other subsection (d) hospital. This written verification could be a brief letter to the MAC stating that the hospital continues to meet the low-volume hospital mileage criterion as documented in a prior low-volume hospital status request. We also are proposing that if a hospital's written request for low-volume hospital status for FY 2017 is received after September 1, 2016, and if the MAC determines that the hospital meets the criteria to qualify as a low-volume hospital, the MAC would apply the applicable low-volume hospital payment adjustment to determine the payment for the hospital's FY 2017 discharges effective prospectively within 30 days of the date of its low-volume hospital status determination, consistent with past practice. (For additional details on our established process for the low-volume hospital payment adjustment, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53408) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50000 through 50001).)

We note that, in the FY 2016 IPPS interim final rule with comment period (80 FR 49595), we revised the regulations at § 412.101 to conform the text to the provisions of section 204 of the MACRA, which extended the changes to the qualifying criteria and the payment adjustment methodology for low-volume hospitals through FY 2017 (that is, through September 30, 2017). We intend to finalize the low-volume hospital provisions (as well as the Medicare-dependent small rural hospital (MDH) provisions at § 412.108) included in that FY 2016 interim final rule with comment period in the FY 2017 IPPS/LTCH PPS final rule.

E. Indirect Medical Education (IME) Payment Adjustment Factor for FY 2017 (§ 412.105)

1. IME Adjustment for FY 2017

Under the IPPS, an additional payment amount is made to hospitals with residents in an approved graduate medical education (GME) program in order to reflect the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The payment amount is determined by use of a statutorily specified adjustment factor. The regulations regarding the calculation of this additional payment, known as the IME adjustment, are located at § 412.105. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51680) for a full discussion of the IME adjustment and IME adjustment factor. Section 1886(d)(5)(B)(ii)(XII) of the Act provides that, for discharges occurring during FY 2008 and fiscal years thereafter, the IME formula multiplier is 1.35. Accordingly, for discharges occurring during FY 2017, the formula multiplier is 1.35. We estimate that application of this formula multiplier for the FY 2017 IME adjustment will result in an increase in IPPS payment of 5.5 percent for every approximately 10 percent increase in the hospital's resident to bed ratio.

2. Other Proposed Policies Related to IME

We refer readers to section IV.I. of the preamble of this proposed rule for a discussion of the proposed policy changes relating to medical residency training programs (or rural tracks) at urban hospitals that also affect payments for IME.

F. Proposed Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2017 and Subsequent Years (§ 412.106)

1. General Discussion

Section 1886(d)(5)(F) of the Act provides for additional Medicare payments to subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. The Act specifies two methods by which a hospital may qualify for the Medicare disproportionate share hospital (DSH) adjustment. Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to needy patients with low incomes. This method is commonly referred to as the "Pickle method." The second method for qualifying for the DSH payment adjustment, which is the most common, is based on a complex statutory formula under which the DSH payment adjustment is based on the hospital's geographic designation, the number of beds in the hospital, and the level of the hospital's disproportionate patient percentage (DPP). A hospital's DPP is the sum of two fractions: the "Medicare fraction" and the "Medicaid fraction." The Medicare fraction (also known as the "SSI fraction" or "SSI ratio") is computed by dividing the number of the hospital's inpatient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits by the hospital's total number of patient days furnished to patients entitled to benefits under Medicare Part A. The Medicaid fraction is computed by dividing the hospital's number of inpatient days furnished to patients who, for such days, were eligible for Medicaid, but were not entitled to benefits under Medicare Part A, by the hospital's total number of inpatient days in the same period.

Because the DSH payment adjustment is part of the IPPS, the DSH statutory references (under section 1886(d)(5)(F) of the Act) to "days" apply only to hospital acute care inpatient days. Regulations located at § 412.106 govern the Medicare DSH payment adjustment and specify how the DPP is calculated as well as how beds and patient days are counted in determining the Medicare DSH payment adjustment. Under § 412.106(a)(1)(i), the number of beds for the Medicare DSH payment adjustment is determined in accordance with bed counting rules for the IME adjustment under § 412.105(b).

Section 3133 of the Patient Protection and Affordable Care Act, as amended by section 10316 of the same Act and section 1104 of the Health Care and Education Reconciliation Act (Pub. L. 111–152), added a new section 1886(r) to the Act that modifies the methodology for computing the Medicare DSH payment adjustment. (For purposes of this proposed rule, we refer to these provisions collectively as section 3133 of the Affordable Care Act.) Beginning with discharges in FY 2014, hospitals that qualify for Medicare DSH payments under section 1886(d)(5)(F) of the Act receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments. This provision applies equally to hospitals that qualify for DSH payments under section 1886(d)(5)(F)(i)(I) of the Act and those hospitals that qualify under the Pickle method under section 1886(d)(5)(F)(i)(II) of the Act.

The remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals under age 65 who are uninsured, is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The payments to each hospital for a fiscal year are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all hospitals that receive Medicare DSH payments for that fiscal year.

As provided by section 3133 of the Affordable Care Act, section 1886(r) of the Act requires that, for FY 2014 and each subsequent fiscal year, a subsection (d) hospital that would otherwise receive DSH payments made under section 1886(d)(5)(F) of the Act receives two separately calculated payments. Specifically, section 1886(r)(1) of the Act provides that the Secretary shall pay to such a subsection (d) hospital (including a Pickle hospital) 25 percent of the amount the hospital would have received under section 1886(d)(5)(F) of the Act for DSH payments, which represents the empirically justified amount for such payment, as determined by the MedPAC in its March 2007 Report to the Congress. We refer to this payment as the "empirically justified Medicare DSH payment."

In addition to this empirically justified Medicare DSH payment, section 1886(r)(2) of the Act provides that, for FY 2014 and each subsequent fiscal year, the Secretary shall pay to such subsection (d) hospital an additional amount equal to the product of three factors. The first factor is the difference between the aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if subsection (r) did not apply and the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for each fiscal year. Therefore, this factor amounts to 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act.

The second factor is, for FYs 2014 through 2017, 1 minus the percent change in the percent of individuals under the age of 65 who are uninsured, determined by comparing the percent of such individuals who were uninsured in 2013, the last year before coverage expansion under the Affordable Care Act (as calculated by the Secretary based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Health Care and Education Reconciliation Act of 2010 that, if determined in the affirmative, would clear such Act for enrollment), and the percent of individuals who were uninsured in the most recent period for which data are available (as so calculated) minus 0.1 percentage point for FY 2014, and minus 0.2 percentage point for FYs 2015 through 2017. For FYs 2014 through 2017, the baseline for the estimate of the change in uninsurance is fixed by the most recent estimate of the Congressional Budget Office before the final vote on the Health Care and Education Reconciliation Act of 2010, which is contained in a March 20, 2010 letter from the Director of the Congressional Budget Office to the Speaker of the House. (The March 20, 2010 letter is available for viewing on the following Web site: *http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/113xx/doc11379/amendreconprop.pdf.*)

For FY 2018 and subsequent fiscal years, the second factor is 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS), and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified), minus 0.2 percentage point for FYs 2018 and 2019. Therefore, for FY 2018 and subsequent fiscal years, the statute provides some greater flexibility in the choice of the data sources to be used for the estimate of the change in the percent of uninsured individuals.

The third factor is a percent that, for each subsection (d) hospital, represents the quotient of the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data), including the use of alternative data where the Secretary determines that alternative data are available which are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, and the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act. Therefore, this third factor represents a hospital's uncompensated care amount for a given time period relative to the uncompensated care amount for that same time period for all hospitals that receive Medicare DSH payments in the applicable fiscal year, expressed as a percent.

For each hospital, the product of these three factors represents its additional payment for uncompensated care for the applicable fiscal year. We refer to the additional payment determined by these factors as the "uncompensated care payment."

Section 1886(r) of the Act applies to FY 2014 and each subsequent fiscal year. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50620 through 50647) and the FY 2014 IPPS interim final rule with comment period (78 FR 61191 through 61197), we set forth our policies for implementing the required changes to the Medicare DSH payment methodology made by section 3133 of the Affordable Care Act for FY 2014. In those rules, we noted that, because section 1886(r) of the Act modifies the payment required under section 1886(d)(5)(F) of the Act, it affects only the DSH payment under the operating IPPS. It does not revise or replace the capital IPPS DSH payment provided under the regulations at 42 CFR part 412, subpart M, which were established through the exercise of the Secretary's discretion in implementing the capital IPPS under section 1886(g)(1)(A) of the Act.

Finally, section 1886(r)(3) of the Act provides that there shall be no administrative or judicial review under section 1869, section 1878, or otherwise of any estimate of the Secretary for purposes of determining the factors described in section 1886(r)(2) of the Act or of any period selected by the Secretary for the purpose of determining those factors. Therefore, there is no administrative or judicial review of the estimates developed for purposes of applying the three factors used to determine uncompensated care payments, or the periods selected in order to develop such estimates.

2. Eligibility for Empirically Justified Medicare DSH Payments and Uncompensated Care Payments

As indicated earlier, the payment methodology under section 3133 of the Affordable Care Act applies to "subsection (d) hospitals" that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act. Therefore, hospitals must receive empirically justified Medicare DSH payments in a fiscal year in order to receive an additional Medicare uncompensated care payment for that year. Specifically, section 1886(r)(2) of the Act states that, in addition to the payment made to a subsection (d) hospital under section 1886(r)(1) of the Act, the Secretary shall pay to such subsection (d) hospitals an additional amount. Because section 1886(r)(1) of the Act refers to empirically justified Medicare DSH payments, the additional payment under section 1886(r)(2) of the Act is limited to hospitals that receive empirically justified Medicare DSH payments in accordance with section 1886(r)(1) of the Act for the applicable fiscal year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and the FY 2014 IPPS interim final rule with comment period (78 FR 61193), we provided that hospitals that are not eligible to receive empirically justified Medicare DSH payments in a fiscal year will not receive uncompensated care payments for that year. We also specified that we would make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the most recent data that are available). We indicated that our final determination on the hospital's eligibility for uncompensated care payments would be based on the hospital's actual DSH status at cost report settlement for that payment year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50006), we specified our policies for several specific classes of hospitals within the scope of section 1886(r) of the Act. We refer readers to those two final rules for a detailed discussion of our policies. In summary, we specified the following:

- *Subsection (d) Puerto Rico hospitals* that are eligible for DSH payments also are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the new payment methodology (78 FR 50623 and 79 FR 50006).
- *Maryland hospitals* are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the payment methodology of section 1886(r) of the Act because they are not paid under the IPPS. As discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50007), effective January 1, 2014, the State of Maryland elected to no longer have Medicare pay Maryland hospitals in accordance with section 1814(b)(3) of the Act and entered into an agreement with CMS that Maryland hospitals will be paid under the Maryland All-Payer Model. However, under the Maryland All-Payer Model, Maryland hospitals still are not paid under the IPPS. Therefore, they remain ineligible to receive empirically justified Medicare DSH payments or uncompensated care payments under section 1886(r) of the Act.
- *SCHs that are paid under their hospital-specific rate* are not eligible for Medicare DSH payments. SCHs that are paid under the IPPS Federal rate receive interim payments based on what we estimate and project their DSH status to be prior to the beginning of the Federal fiscal year (based on the best available data at that time) subject to settlement through the cost report, and if they receive interim empirically justified Medicare DSH payments in a fiscal year, they also will receive interim uncompensated care payments for that fiscal year on a per discharge basis, subject as well to settlement through the cost report. Final eligibility determinations will be made at the end of the cost reporting period at settlement, and both interim empirically justified Medicare DSH payments and uncompensated care payments will be adjusted accordingly (78 FR 50624 and 79 FR 50007).
- *MDHs* are paid based on the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years (76 FR 51684). The IPPS Federal rate used in the MDH payment methodology is the same IPPS Federal rate that is used in the SCH payment methodology. Section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Public Law 114–10, enacted April 16, 2015, extended the MDH program for discharges on or after April 1, 2015, through September 30, 2017. Because MDHs are paid based on the IPPS Federal rate, for FY 2017, MDHs will continue to be eligible to receive empirically justified Medicare DSH payments and uncompensated care payments if their DPP is at least 15 percent. We will apply the same process to determine MDHs' eligibility for empirically justified Medicare DSH and uncompensated care payments, as we do for all other IPPS hospitals, through September 30, 2017. Moreover, we will continue to make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the most recent data that are available). Our final determination on the hospital's eligibility for uncompensated care payments will be based on the hospital's actual DSH status at cost report settlement for that payment year. In addition, as we do for all IPPS hospitals, we calculate a numerator for Factor 3 for all MDHs, regardless of whether they are projected to be eligible for Medicare DSH payments during the fiscal year, but the denominator for Factor 3 will be based on the uncompensated care data from the hospitals that we have projected to be eligible for Medicare DSH payments during the fiscal year.
- *IPPS hospitals that have elected to participate in the Bundled Payments for Care Improvement initiative* continue to be paid under the IPPS (77 FR 53342) and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments (78 FR 50625 and 79 FR 50008).
- *Hospitals participating in the Rural Community Hospital Demonstration Program* under section 410A of the Medicare Modernization Act do not receive DSH payments and, therefore, are excluded from receiving empirically justified Medicare DSH payments and uncompensated care payments under the new DSH payment methodology (78 FR 50625 and 79 FR 50008). There are 14 hospitals currently participating in the program; 10 will continue to participate through the end of FY 2016, and 4 will continue to participate through the scheduled end of the program on December 31, 2016. Once a hospital's participation in the demonstration program ends, the hospital will be treated like a subsection (d) hospital and subject to the IPPS. Therefore, once their participation ends, these hospitals could be eligible to receive empirically justified Medicare DSH payments and uncompensated care payments and, if so, will be treated accordingly for interim and final payments. We will apply the same process to determining their eligibility as we do for all other IPPS hospitals, and will make interim and final DSH and uncompensated care payments accordingly.

3. Empirically Justified Medicare DSH Payments

As we have discussed earlier, section 1886(r)(1) of the Act requires the Secretary to pay 25 percent of the amount of the Medicare DSH payment that would otherwise be made under section 1886(d)(5)(F) of the Act to a subsection (d) hospital. Because section 1886(r)(1) of the Act merely requires the program to pay a designated percentage of these payments, without revising the criteria governing eligibility for DSH payments or the underlying payment methodology, we stated in the FY 2014 IPPS/LTCH PPS final rule that we did not believe that it was necessary to develop any new operational mechanisms for making such payments. Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50626), we implemented this provision by advising MACs to simply adjust the interim claim payments to the requisite 25 percent of what would have otherwise been paid. We also made corresponding changes to the hospital cost report so that these empirically justified Medicare DSH payments can be settled at the appropriate level at the time of cost report settlement. We provided more detailed operational instructions and cost report instructions following issuance of the FY 2014 IPPS/LTCH PPS final rule that are available on the CMS Web site at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals-Items/R5P240.html.*

4. Uncompensated Care Payments

As we have discussed earlier, section 1886(r)(2) of the Act provides that, for each eligible hospital in FY 2014 and subsequent years, the uncompensated care payment is the product of three factors. These three factors represent our estimate of 75 percent of the amount of Medicare DSH payments that would otherwise have been paid, an adjustment to this amount for the percent change in the national rate of uninsurance compared to the rate of uninsurance in 2013, and each eligible hospital's estimated uncompensated care amount relative to the estimated uncompensated care amount for all eligible hospitals. Below we discuss the data sources and methodologies for computing each of these factors, our final policies for FYs 2014 through 2016, and our proposed policies for FY 2017.

a. Calculation of Proposed Factor 1 for FY 2017

Section 1886(r)(2)(A) of the Act establishes Factor 1 in the calculation of the uncompensated care payment. Section 1886(r)(2)(A) of the Act states that this factor is equal to the difference between (1) the aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year (as estimated by the Secretary); and (2) the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year (as so estimated). Therefore, section 1886(r)(2)(A)(i) of the Act represents the estimated Medicare DSH payments that would have been made under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year. Under a prospective payment system, we would not know the precise aggregate Medicare DSH payment amount that would be paid for a Federal fiscal year until cost report settlement for all IPPS hospitals is completed, which occurs several years after the end of the Federal fiscal year. Therefore, section 1886(r)(2)(A)(i) of the Act provides authority to estimate this amount, by specifying that, for each fiscal year to which the provision applies, such amount is to be estimated by the Secretary. Similarly, section 1886(r)(2)(A)(ii) of the Act represents the estimated empirically justified Medicare DSH payments to be made in a fiscal year, as prescribed under section 1886(r)(1) of the Act. Again, section 1886(r)(2)(A)(ii) of the Act provides authority to estimate this amount.

Therefore, Factor 1 is the difference between our estimates of: (1) The amount that would have been paid in Medicare DSH payments for the fiscal year, in the absence of the new payment provision; and (2) the amount of empirically justified Medicare DSH payments that are made for the fiscal year, which takes into account the requirement to pay 25 percent of what would have otherwise been paid under section 1886(d)(5)(F) of the Act. In other words, this factor represents our estimate of 75 percent (100 percent minus 25 percent) of our estimate of Medicare DSH payments that would otherwise be made, in the absence of section 1886(r) of the Act, for the fiscal year.

As we did for FY 2016, in order to determine Factor 1 in the uncompensated care payment formula for FY 2017, we are proposing to continue the policy established in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50628 through 50630) and in the FY 2014 IPPS interim final rule with comment period (78 FR 61194) of determining Factor 1 by developing estimates of both the aggregate amount of Medicare DSH payments that would be made in the absence of section 1886(r)(1) of the Act and the aggregate amount of empirically justified Medicare DSH payments to hospitals under 1886(r)(1) of the Act. These estimates will not be revised or updated after we know the final Medicare DSH payments for FY 2017.

Therefore, in order to determine the two elements of Factor 1 for FY 2017 (Medicare DSH payments *prior* to the application of section 1886(r)(1) of the Act, and empirically justified Medicare DSH payments *after* application of section 1886(r)(1) of the Act), we used the most recently available projections of Medicare DSH payments for the fiscal year, as calculated by CMS' Office of the Actuary using the most recently filed Medicare hospital cost report with Medicare DSH payment information and the most recent Medicare DSH patient percentages and Medicare DSH payment adjustments provided in the IPPS Impact File.

For purposes of calculating Factor 1 and modeling the impact of this FY 2017 IPPS/LTCH PPS proposed rule, we used the Office of the Actuary's March 2016 Medicare DSH estimates, which are based on data from the December 2015 update of the Medicare Hospital Cost Report Information System (HCRIS) and the FY 2016 IPPS/LTCH PPS final rule IPPS Impact file, published in conjunction with the publication of the FY 2016 IPPS/LTCH PPS final rule. Because SCHs that are projected to be paid under their hospital-specific rate are excluded from the application of section 1886(r) of the Act, these hospitals also were excluded from the March 2016 Medicare DSH estimates. Furthermore, because section 1886(r) of the Act specifies that the uncompensated care payment is in addition to the empirically justified Medicare DSH payment (25 percent of DSH payments that would be made without regard to section 1886(r) of the Act), Maryland hospitals participating in the Maryland All-Payer Model that do not receive DSH payments are also excluded from the Office of the Actuary's Medicare DSH estimates. Because the Rural Community Hospital Demonstration program is scheduled to end on December 31, 2016, hospitals that are participating in the program are included in this estimate for FY 2017. However, we have excluded 25 percent of our estimate of DSH payments that would otherwise be made to the 4 hospitals whose participation in the program will continue through December 31, 2016, as these hospitals will be excluded from receiving DSH payments until that time. The estimate includes the total DSH payments that would be made to the 10 hospitals whose participation in the Rural Community Hospital Demonstration program will continue only through September 30, 2016.

Using the data sources discussed above, the Office of the Actuary uses the most recently submitted Medicare cost report data to identify Medicare DSH payments and the most recent Medicare DSH payment adjustments provided in the IPPS Impact File, and applies inflation updates and assumptions for future changes in utilization and case-mix to estimate Medicare DSH payments for the upcoming fiscal year. The March 2016 Office of the Actuary estimate for Medicare DSH payments for FY 2017, without regard to the application of section 1886(r)(1) of the Act, is approximately $14.227 billion. This estimate excludes Maryland hospitals participating in the Maryland All-Payer Model, SCHs paid under their hospital-specific payment rate, and 25 percent of payments to the 4 hospitals whose participation in the Rural Community Hospital Demonstration program will continue through December 31, 2016. Therefore, based on the March 2016 estimate, the estimate for empirically justified Medicare DSH payments for FY 2017, with the application of section 1886(r)(1) of the Act, is approximately $3.556 billion (or 25 percent of the total amount of estimated Medicare DSH payments for

FY 2017). Under § 412.106(g)(1)(i) of the regulations, Factor 1 is the difference between these two estimates of the Office of the Actuary. Therefore, in this proposed rule, we are proposing that Factor 1 for FY 2017 is $10,670,529,595.84, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2017 ($14,227,372,794.46 minus $3,556,843,198.62).

The Office of the Actuary's estimates for FY 2017 begin with a baseline of $12.154 billion in Medicare DSH expenditures for FY 2013. The following table shows the factors applied to update this baseline through the current estimate for FY 2017:

FACTORS APPLIED FOR FY 2014 THROUGH FY 2017 TO ESTIMATE MEDICARE DSH EXPENDITURES USING 2013 BASELINE

FY	Update	Discharge	Case-mix	Other	Total	Estimated DSH payment (in billions)
2014	1.009	0.9553	1.015	1.04795	1.025268	$12.461
2015	1.014	0.9894	1.005	1.0702	1.079048	13.446
2016	1.009	1.0078	1.005	0.9993	1.021239	13.732
2017	1.0005	1.0168	1.005	1.0134	1.036095	14.227

In this table, the discharge column shows the increase in the number of Medicare FFS inpatient hospital discharges. The figures for FYs 2014 and 2015 are based on Medicare claims data that have been adjusted by a completion factor. The discharge figure for FY 2016 is based on preliminary data for 2016. The discharge figure for FY 2017 is an assumption based on recent trends recovering back to the long-term trend and assumptions related to how many beneficiaries will be enrolled in Medicare Advantage (MA) plans. The case-mix column shows the increase in case-mix for IPPS hospitals. The case-mix figures for FYs 2014 and 2015 are based on actual data adjusted by a completion factor. The FY 2016 and FY 2017 increases are based on the recommendation of the 2010–2011 Medicare Technical Review Panel. The "other" column shows the increase in other factors that contribute to the Medicare DSH estimates. These factors include the difference between the total inpatient hospital discharges and the IPPS discharges, various adjustments to the payment rates that have been included over the years but are not reflected in the other columns (such as the change in rates for the 2-midnight stay policy). In addition, the "other" column includes a factor for the Medicaid expansion due to the Affordable Care Act.

The table below shows the factors that are included in the "Update" column of the above table:

FY	Market basket percentage	Affordable Care Act payment reductions	Multifactor productivity adjustment	Documentation and coding	Total update percentage
2014	2.5	−0.3	−0.5	−0.8	0.9
2015	2.9	−0.2	−0.5	−0.8	1.4
2016	2.4	−0.2	−0.5	−0.8	0.9
2017	2.8	−0.75	−0.5	−1.5	0.05

Note: All numbers are based on the FY 2017 President's Budget projections.

b. Calculation of Proposed Factor 2 for FY 2017

Section 1886(r)(2)(B) of the Act establishes Factor 2 in the calculation of the uncompensated care payment. Specifically, section 1886(r)(2)(B)(i) of the Act provides that, for each of FYs 2014, 2015, 2016, and 2017, a factor equal to 1 minus the percent change in the percent of individuals under the age of 65 who are uninsured, as determined by comparing the percent of such individuals (1) who were uninsured in 2013, the last year before coverage expansion under the Affordable Care Act (as calculated by the Secretary based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Health Care and Education Reconciliation Act of 2010 that, if determined in the affirmative, would clear such Act for enrollment); and (2) who are uninsured in the most recent period for which data are available (as so calculated), minus 0.1 percentage point for FY 2014 and minus 0.2 percentage point for each of FYs 2015, 2016, and 2017.

Section 1886(r)(2)(B)(i)(I) of the Act further indicates that the percent of individuals under 65 without insurance in 2013 must be the percent of such individuals who were uninsured in 2013, the last year before coverage expansion under the Affordable Care Act (as calculated by the Secretary based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Health Care and Education Reconciliation Act of 2010 that, if determined in the affirmative, would clear such Act for enrollment). The Health Care and Education Reconciliation Act (Pub. L. 111–152) was enacted on March 30, 2010. It was passed in the House of Representatives on March 21, 2010, and by the Senate on March 25, 2010. Because the House of Representatives was the first House to vote on the Health Care and Education Reconciliation Act of 2010 on March 21, 2010, we have determined that the most recent estimate available from the Director of the Congressional Budget Office "*before* a vote in either House on the Health Care and Education Reconciliation Act of 2010 . . ." (emphasis added) appeared in a March 20, 2010 letter from the director of the CBO to the Speaker of the House. Therefore, we believe that only the estimates in this March 20, 2010 letter meet the statutory requirement under section 1886(r)(2)(B)(i)(I) of the Act. (To view the March 20, 2010 letter, we refer readers to the Web site at: *http://*

www.cbo.gov/sites/default/files/cbofiles/ftpdocs/113xx/doc11379/amendreconprop.pdf.)

In its March 20, 2010 letter to the Speaker of the House of Representatives, the CBO provided two estimates of the "post-policy uninsured population." The first estimate is of the "Insured Share of the Nonelderly Population Including All Residents" (82 percent) and the second estimate is of the "Insured Share of the Nonelderly Population Excluding Unauthorized Immigrants" (83 percent). In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50631), we used the first estimate that includes all residents, including unauthorized immigrants. We stated that we believe this estimate is most consistent with the statute, which requires us to measure "the percent of individuals under the age of 65 who are uninsured" and provides no exclusions except for individuals over the age of 65. In addition, we stated that we believe that this estimate more fully reflects the levels of uninsurance in the United States that influence uncompensated care for hospitals than the estimate that reflects only legal residents. The March 20, 2010 CBO letter reports these figures as the estimated percentage of individuals with insurance. However, because section 1886(r)(2)(B)(i) of the Act requires that we compare the percent of individuals who are uninsured in the most recent period for which data are available with the percent of individuals who were uninsured in 2013, in the FY 2014 IPPS/LTCH PPS final rule, we used the CBO insurance rate figure and subtracted that amount from 100 percent (that is the total population without regard to insurance status) to estimate the 2013 baseline percent of individuals without insurance. Therefore, for FYs 2014 through 2017, our estimate of the uninsurance percentage for 2013 is 18 percent.

Section 1886(r)(2)(B)(i) of the Act requires that we compare the baseline uninsurance rate to the percent of such individuals who are uninsured in the most recent period for which data are available (as so calculated). In the FY 2014, FY 2015, and FY 2016 IPPS/LTCH PPS final rules (78 FR 50634, 79 FR 50014, and 80 FR 49522, respectively), we used the same data source, CBO estimates, to calculate this percent of individuals without insurance. In response to public comments, we also agreed that we should normalize the CBO estimates, which are based on the calendar year, for the Federal fiscal years for which each calculation of Factor 2 is made (78 FR 50633). Therefore, for this FY 2017 IPPS/LTCH PPS proposed rule, we used the most recently available estimate of the uninsurance rate, which is based on the CBO's March 2015 estimates of the effects of the Affordable Care Act on health insurance coverage (which are available at *http://www.cbo.gov/sites/default/files/cbofiles/attachments/43900–2014–04–ACAtables2.pdf*). The CBO's March 2015 estimate of individuals under the age of 65 with insurance in CY 2016 is 89 percent. Therefore, the CBO's most recent estimate of the rate of uninsurance in CY 2016 is 11 percent (that is, 100 percent minus 89 percent). Similarly, the CBO's March 2015 estimate of individuals under the age of 65 with insurance in CY 2017 is 90 percent. Therefore, the CBO's most recent estimate of the rate of uninsurance in CY 2017 available for this proposed rule is 10 percent (that is, 100 percent minus 90 percent).

The calculation of the proposed Factor 2 for FY 2017, employing a weighted average of the CBO projections for CY 2016 and CY 2017, is as follows:

- CY 2016 rate of insurance coverage (March 2015 CBO estimate): 89 percent.
- CY 2017 rate of insurance coverage (March 2015 CBO estimate): 90 percent.
- FY 2016 rate of insurance coverage: (89 percent * .25) + (90 percent * .75) = 89.75 percent.
- Percent of individuals without insurance for 2013 (March 2010 CBO estimate): 18 percent.
- Percent of individuals without insurance for FY 2017 (weighted average): 10.25 percent.

$1-|((0.1025-0.18)/0.18)| = 1 - 0.4306 = 0.5694$ (56.94 percent)

0.5694 (56.94 percent) − .002 (0.2 percentage points for FY 2017 under section 1886(r)(2)(B)(i) of the Act) = 0.5674 or 56.74 percent

0.5674 = Factor 2

Therefore, the proposed Factor 2 for FY 2017 is 56.74 percent.

The FY 2017 Proposed Uncompensated Care Amount is: $10,670,529,595.84 × 0.5674 = $6,054,458,492.68.

FY 2017 Proposed Uncompensated Care Total Available	$6,054,458,492.68

c. Calculation of Proposed Factor 3 for FY 2017

Section 1886(r)(2)(C) of the Act defines Factor 3 in the calculation of the uncompensated care payment. As we have discussed earlier, section 1886(r)(2)(C) of the Act states that Factor 3 is equal to the percent, for each subsection (d) hospital, that represents the quotient of (1) the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data (including, in the case where the Secretary determines alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, the use of such alternative data)); and (2) the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period (as so estimated, based on such data).

Therefore, Factor 3 is a hospital-specific value that expresses the proportion of the estimated uncompensated care amount for each subsection (d) hospital and each subsection (d) Puerto Rico hospital with the potential to receive Medicare DSH payments relative to the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the fiscal year for which the uncompensated care payment is to be made. Factor 3 is applied to the product of Factor 1 and Factor 2 to determine the amount of the uncompensated care payment that each eligible hospital will receive for FY 2014 and subsequent fiscal years. In order to implement the statutory requirements for this factor of the uncompensated care payment formula, it was necessary to determine: (1) The definition of uncompensated care or, in other words, the specific items that are to be included in the numerator (that is, the estimated uncompensated care amount for an individual hospital) and the denominator (that is, the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the applicable fiscal year); (2) the data source(s) for the estimated uncompensated care amount; and (3) the timing and manner of computing the quotient for each hospital estimated to receive Medicare DSH payments. The statute instructs the Secretary to estimate the amounts of uncompensated care for a period based on appropriate data. In addition, we note that the statute permits the

Secretary to use alternative data in the case where the Secretary determines that such alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured.

In the course of considering how to determine Factor 3 during the rulemaking process for FY 2014, we considered defining the amount of uncompensated care for a hospital as the uncompensated care costs of each hospital and determined that Worksheet S–10 of the Medicare cost report potentially provides the most complete data regarding uncompensated care costs for Medicare hospitals. However, because of concerns regarding variations in the data reported on the Worksheet S–10 and the completeness of these data, we did not propose to use data from the Worksheet S–10 to determine the amount of uncompensated care for FY 2014, the first year this provision was in effect, or for FY 2015 and FY 2016. We instead employed the utilization of insured low income patients, defined as inpatient days of Medicaid patients plus inpatient days of Medicare SSI patients as defined in § 412.106(b)(4) and § 412.106(b)(2)(i) of the regulations, respectively, to determine Factor 3. We believed that these alternative data, which are currently reported on the Medicare cost report, would be a better proxy for the amount of uncompensated care provided by hospitals. We also indicated that we were expecting reporting on the Worksheet S–10 to improve over time and remained convinced that the Worksheet S–10 could ultimately serve as an appropriate source of more direct data regarding uncompensated care costs for purposes of determining Factor 3. As discussed in section IV.F.3.d. of the preamble of this proposed rule, since the introduction of the uncompensated care payment in FY 2014, we believe that hospitals have been submitting more accurate and consistent data through Worksheet S–10 and that it is appropriate to begin incorporating Worksheet S–10 data for purposes of calculating Factor 3 starting in FY 2018. As discussed in greater detail in section IV.F.3.d. of the preamble of this proposed rule, we are proposing a methodology and timeline for incorporating Worksheet S–10 data and invite public comments on such a proposal.

For FY 2017, we believe it remains premature to propose the use of Worksheet S–10 data for purposes of determining Factor 3 because hospitals were not on notice that Worksheet S–10 would be used for purposes of computing uncompensated care payments prior to FY 2014, which could affect the accuracy and completeness of the information reported on Worksheet S–10. As described more fully below regarding the time period of the data used to calculate Factor 3, for FY 2017, we are using data from hospital cost reports that precede FY 2014 to determine Factor 3 of the uncompensated care payments methodology. Therefore, for FY 2017, we remain concerned about the accuracy and consistency of the data reported on Worksheet S–10 and are proposing to continue to employ the utilization of insured low-income patients (defined as inpatient days of Medicaid patients plus inpatient days of Medicare SSI patients as defined in § 412.106(b)(4) and § 412.106(b)(2)(i), respectively) to determine Factor 3. We also are proposing to continue the policies that were finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50020) to address several specific issues concerning the process and data to be employed in determining Factor 3 in the case of hospital mergers for FY 2017 and subsequent fiscal years.

We also are proposing to make a change to the data that will be used to calculate Factor 3 for Puerto Rico hospitals. We received a comment in response to the FY 2016 IPPS/LTCH PPS proposed rule that requested CMS to create a proxy for the SSI days used in the Factor 3 calculation for Puerto Rico hospitals (80 FR 49526). Specifically, commenters were concerned that residents of Puerto Rico are not eligible for SSI benefits. Although we did not have logical outgrowth to adopt any change for FY 2016, we indicated that we planned to address this issue in the FY 2017 IPPS/LTCH PPS proposed rule if we also proposed to continue using inpatient days of Medicare SSI patients as a proxy for uncompensated care in FY 2017. Because we are proposing to continue using insured low-income patient days as a proxy for uncompensated care in FY 2017, we believe it is important to consider the commenter's request regarding the data used to calculate Factor 3 for Puerto Rico hospitals. Accordingly, we are proposing to create a proxy for SSI days for Puerto Rico hospitals for use in the Factor 3 calculation. The commenter specifically mentioned the use of inpatient days for Medicare beneficiaries receiving Medicaid as this proxy. We have examined this concept and have been unable to identify a systematic source for these data for Puerto Rico hospitals. Specifically, we note that inpatient utilization for Medicare beneficiaries entitled to Medicaid is not reported by hospitals on the Medicare cost report. Therefore, we sought an alternative method using publicly available Medicare data for determining a proxy to account for the fact that residents of Puerto Rico are not eligible for SSI, and therefore Puerto Rico hospitals have a relatively low number of Medicare SSI days in the Factor 3 computation. We believe it is appropriate to use data from the Medicare cost report to develop a Puerto Rico Medicare SSI days proxy because they are publicly available, used for payment purposes, and subject to audit. However, we acknowledge that there are other data sources that could be included to develop such a proxy, in particular the SSI ratios posted on the Medicare DSH Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html*, and therefore are soliciting public comment on their use.

To develop a Puerto Rico Medicare SSI days proxy using data from the Medicare cost report, our Office of the Actuary examined data from 2013 cost reports and analyzed the relationship between Medicare SSI days (estimated using SSI ratios on the cost report and Medicare days from the same cost report) and Medicaid days (reported by the hospitals in accordance with § 412.106(b)(4)). Nationally, excluding Puerto Rico, the Office of the Actuary found that, on average and across States, for every 100 Medicaid inpatient days, hospitals had 14 Medicare SSI days. In other words, the relationship between Medicare SSI days and Medicaid days reported by hospitals in States, excluding Puerto Rico, was approximately 14 percent. We believe it would be appropriate to extrapolate this relationship to Puerto Rico hospitals to approximate how many patient days for these hospitals would be Medicare SSI days if Puerto Rico residents were eligible to receive SSI. Therefore, to calculate Factor 3 for FY 2017, we are proposing to use a proxy for Medicare SSI days for each Puerto Rico hospital equal to 14 percent (or 0.14) of its Medicaid days. In other words, for each Puerto Rico hospital, we would compute a value that is equal to 14 percent of its Medicaid days, where Medicaid days are determined in accordance with § 412.106(b)(4). Because this is a proposed proxy for the Puerto Rico hospital's Medicare SSI days, this value would replace whatever value would otherwise be computed for the hospital under § 412.106(b)(2)(i). Specifically, we would first remove any Medicare SSI days that a Puerto Rico hospital has from our calculation for purposes of determining the numerator of Factor 3 for the hospital and, if the hospital is projected to be eligible for DSH payments in FY 2017, the denominator of Factor 3. Second, we would add the proxy to the hospital's Medicaid days for purposes of determining the numerator of Factor 3 for the hospital and, if the hospital is projected to be eligible for DSH payments in FY 2017, the denominator of Factor 3. We note that we continue to encourage Puerto Rico hospitals to report uncompensated care costs on Worksheet S–10 of the Medicare cost report completely and accurately in light of our proposal to begin incorporating data from Worksheet S–10 in the computation of hospitals' uncompensated care payments starting in FY 2018, as described in more detail in section IV.F.3.d. of the preamble of this proposed rule.

In summary, we are inviting public comments on these proposals to continue to use insured low-income days (that is, to use data for Medicaid and Medicare SSI patient days determined in accordance with § 412.106(b)(2)(i) and (b)(4) as a proxy for uncompensated care, as permitted by statute, including a proxy for Medicare SSI days for Puerto Rico hospitals), to determine Factor 3 for FY 2017. These proposals would be codified in our regulations at § 412.106(g)(1)(iii)(C). We also are inviting public comments on our proposal to continue the policies concerning the process and data to be employed in determining Factor 3 in the case of hospital mergers.

As we have done for every proposed rule beginning in FY 2014, for this FY 2017 IPPS/LTCH PPS proposed rule, we are publishing on the CMS Web site a table listing Factor 3 for all hospitals that we estimate would receive empirically justified Medicare DSH payments in FY 2017 (that is, hospitals that we project would receive interim uncompensated care payments during the fiscal year), and for the remaining subsection (d) hospitals and subsection (d) Puerto Rico hospitals that have the potential of receiving a Medicare DSH payment in the event that they receive an empirically justified Medicare DSH payment for the fiscal year as determined at cost report settlement. This table also contains a list of the mergers that we are aware of and the computed uncompensated care payment for each merged hospital. Hospitals have 60 days from the date of public display of this FY 2017 IPPS/LTCH PPS proposed rule to review this table and notify CMS in writing of any inaccuracies. Comments can be submitted to the CMS inbox at *Section3133DSH@cms.hhs.gov.* After the publication of the FY 2017 IPPS/LTCH final rule, hospitals will have until August 31, 2016, to review and submit comments on the accuracy of the table published in conjunction with the final rule. Comments can be submitted to the CMS inbox at *Section3133DSH@cms.hhs.gov* through August 31, 2016, and any changes to Factor 3 will be posted on the CMS Web site prior to October 1, 2016.

The statute also allows the Secretary the discretion to determine the time periods from which we will derive the data to estimate the numerator and the denominator of the Factor 3 quotient. Specifically, section 1886(r)(2)(C)(i) of the Act defines the numerator of the quotient as the amount of uncompensated care for such hospital *for a period selected by the Secretary.* Section 1886(r)(2)(C)(ii) of the Act defines the denominator as the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act *for such period.* In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50638), we adopted a process of making interim payments with final cost report settlement for both the empirically justified Medicare DSH payments and the uncompensated care payments required by section 3133 of the Affordable Care Act. Consistent with that process, we also determined the time period from which to calculate the numerator and denominator of the Factor 3 quotient in a way that would be consistent with making interim and final payments. Specifically, we must have Factor 3 values available for hospitals that we estimate will qualify for Medicare DSH payments and for those hospitals that we do not estimate will qualify for Medicare DSH payments but that may ultimately qualify for Medicare DSH payments at the time of cost report settlement.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50638) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50018), we finalized a policy of using the most recent available full year of Medicare cost report data for determining Medicaid days and the most recently available SSI ratios to calculate Factor 3. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49528), we held constant the cost reporting years used to determine Medicaid days in the calculation of Factor 3. That is, instead of calculating the numerator and the denominator of Factor 3 for hospitals based on the most recently available full year of Medicare cost report data with respect to a Federal fiscal year, we used data from the more recent of the cost report years (2012/2011) used to determine Medicaid days in FY 2015. We made this change in order to refine the balance between the recency and accuracy of the data used in the Factor 3 calculation. Because we make prospective determinations of the uncompensated care payment without reconciliation, we believed this change would increase the accuracy of the data used to determine Factor 3, and accordingly each eligible hospital's allocation of the overall uncompensated care amount by providing hospitals with more time to submit these data before they are used in the computation of Factor 3. As in prior years, if the more recent of the two cost reporting periods did not reflect data for a 12-month period, we used data from the earlier of the two periods so long as that earlier period reflected data for a period of 12 months. If neither of the two periods reflected 12 months, we used the period that reflected a longer amount of time. We also finalized a proposal to continue to extract Medicaid days from the most recent HCRIS database update and to use Medicare SSI days from the most recent SSI ratios available to us during the time of rulemaking to calculate Factor 3. We stated that, for subsequent fiscal years, if we propose and finalize a policy of using insured low-income days in computing Factor 3, we would continue to use the most recent HCRIS database extract at the time of the annual rulemaking cycle, and to use the subsequent year of cost reports (that is, to advance the 12-month cost reports by 1 year). In addition, for any subsequent fiscal years in which we finalize a policy to use insured low-income days to compute Factor 3, our intention would be to continue to use the most recently available SSI ratio data at the time of annual rulemaking to calculate Factor 3. We believed that it was appropriate to state our intentions regarding the specific data we would use in the event Factor 3 was determined on the basis of low-income insured days for subsequent years to provide hospitals with as much guidance as possible so they may best consider how and when to submit cost report information in the future. We noted that we would make proposals with regard to our methodology for calculating Factor 3 for subsequent fiscal years through notice-and-comment rulemaking.

Since the publication of the FY 2016 IPPS/LTCH PPS final rule, we have learned that some members of the hospital community have been disadvantaged by our policy of using only one cost reporting period to determine their share of uncompensated care. Specifically, many hospitals have reported unpredictable swings and anomalies in their low-income insured days between cost reporting periods. These hospitals expressed concern that the use of only one cost reporting period is a poor predictor of their future uncompensated care burden and results in inadequate payments. Because the data used to make uncompensated care payment determinations are not subject to reconciliation after the end of the fiscal year, we believe that it would be appropriate to expand the time period for the data used to calculate Factor 3 from one cost reporting period to three cost reporting periods. Using data from more than one cost reporting period would mitigate undue fluctuations in the amount of uncompensated care payments to hospitals from year to year and smooth over anomalies between cost reporting periods. Moreover, this policy would have the benefit of supplementing the data of hospitals that filed cost reports that are less than 12 months, such that the basis of their uncompensated care payments and those of hospitals that filed full-year 12-month cost reports would be more equitable. We believe that computing Factor 3 using data from three cost reporting periods would best stabilize hospitals' uncompensated care payments while maintaining the recency of the data used in the Factor 3 calculation. We believe that using data from two cost reporting periods would not be as stable while using data from more than three cost reporting periods could result in using overly dated information.

Therefore, for FY 2017, we are proposing to use an average of data derived from three cost reporting periods instead of one cost reporting period to compute Factor 3. That is, we would calculate a Factor 3 for each cost reporting period and calculate the average. We would calculate their average by adding these amounts together, and dividing the sum by three, in order to calculate Factor 3 for FY 2017. Consistent with the policy adopted in the FY 2016 IPPS/LTCH PPS final rule, we would advance the most recent cost report years used to obtain Medicaid days and Medicare SSI days in FY 2017 by one year and continue to extract Medicaid days data from the most recent update of HCRIS, which for FY 2017 would be the March 2015 update of HCRIS. If the hospital does not have data for one or more of the three cost reporting periods, we compute Factor 3 for the periods available and average those. In other words, we would divide the sum of the individual Factor 3s by the number of cost reporting periods for which there are data. If a hospital has merged, we would combine data from both hospitals for the cost reporting periods in which the merger is not reflected in the surviving hospital's cost report data to compute Factor 3 for the surviving hospital. Moreover, to further reduce undue fluctuations in a hospital's uncompensated care payments, if a hospital filed multiple cost reports beginning in the same fiscal year, we are proposing to combine data from the multiple cost reports so that a hospital may have a Factor 3 calculated using more than one cost report within a cost reporting period. We are proposing to codify these changes for FY 2017 by amending the regulations at § 412.106(g)(1)(iii)(C). We are inviting public comments on this proposal, which we describe more fully below.

For the FY 2016 IPPS/LTCH PPS final rule, we used the most recent of hospitals' 12-month 2012 or 2011 cost reports and 2012 cost report data submitted to CMS by IHS hospitals to obtain the Medicaid days to calculate Factor 3. In addition, we used Medicare SSI days from the FY 2013 SSI ratios published on the following CMS Web site to calculate Factor 3: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html*.

Under our proposal to calculate Factor 3 for FY 2017 using data from three cost reporting periods, we would use data from hospitals' FY 2011, FY 2012, and FY 2013 cost reporting periods extracted from the most recent update of the hospital cost report data in the HCRIS database and the FY 2011 and FY 2012 cost report data submitted to CMS by IHS hospitals to obtain the Medicaid days to calculate Factor 3. (We note that, starting with the FY 2013 cost reports, data for IHS hospitals will be included in the HCRIS database and will no longer be submitted separately.) In addition, to calculate Factor 3 for FY 2017, we anticipate that, under our proposal discussed earlier to use the most recent available 3 years of data on Medicare SSI utilization, we would obtain Medicare SSI days from the FY 2012, FY 2013, and FY 2014 SSI ratios (or, for Puerto Rico hospitals, substitute Medicare SSI days with a proxy as described earlier). We expect the FY 2014 SSI ratios to be published on the CMS Web site when available at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html*. Under this proposal, we would calculate Factor 3 as follows:

Step 1: Calculate Factor 3 for FY 2011 by summing a hospital's FY 2011 Medicaid days and FY 2012 SSI days and dividing by all DSH eligible hospitals' FY 2011 Medicaid days and FY 2012 SSI days.

Step 2: Calculate Factor 3 for FY 2012 by summing a hospital's FY 2012 Medicaid days and FY 2013 SSI days and dividing by all DSH eligible hospitals' FY 2012 Medicaid days and FY 2013 SSI days.

Step 3: Calculate Factor 3 for FY 2013 by summing a hospital's FY 2013 Medicaid days and FY 2014 SSI days and dividing by all DSH eligible hospitals' FY 2013 Medicaid days and FY 2014 SSI days.

Step 4: Sum the Factor 3 calculated for FY 2011, FY 2012, and FY 2013 and divide by the number of cost reporting periods with data to compute an average Factor 3.

For illustration purposes, in Table 18 associated with the FY 2017 proposed rule (which is available via the Internet on the CMS Web site), we compute Factor 3 using hospitals' FY 2011, FY 2012, and FY 2013 cost reports from the December 2015 update of HCRIS to obtain Medicaid days and the FY 2012 and FY 2013 SSI ratios published on the following CMS Web site to determine Medicare SSI days: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html*. Because the FY 2014 SSI ratios are not yet available, for purposes of this proposed rule, we computed Factor 3 for FY 2013 using FY 2013 Medicaid days and FY 2013 SSI days. However, we expect that the FY 2014 SSI ratios will be available to calculate Factor 3 for the FY 2017 IPPS/LTCH PPS final rule.

For subsequent years, we are proposing to continue to use the most recent HCRIS database extract at the time of the annual rulemaking cycle and to advance the three cost reporting periods used to determine Factor 3 by 1 year as appropriate. For instance, if we were to finalize a proposal to continue using the proxy in FY 2018, we would use FY 2012, FY 2013, and FY 2014 cost reports from the most recent available extract of HCRIS for Medicaid days and FY 2013, FY 2014, and FY 2015 SSI ratios to obtain the Medicare SSI days and follow the same methodology outlined earlier to determine Factor 3. However, as discussed earlier, we believe that it is possible to begin incorporating data from Worksheet S–10 into the computation of Factor 3 starting in FY 2018 and outline a proposal for doing so using data from three cost reporting periods in the following section.

d. Proposed Calculation of Factor 3 for FY 2018 and Subsequent Years

(1) Background

In response to commenters' requests for a timeline and transition for introducing Worksheet S–10 data into the calculation of Factor 3, in this section, we discuss our proposed plans on how to begin incorporating hospitals' Worksheet S–10 data into the calculation of Factor 3, in order to allocate payments based on a hospital's share of overall uncompensated care costs reported on Worksheet S–10. When we first discussed using Worksheet S–10 to allocate hospitals' shares of uncompensated care costs in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50638), we explained why we believed that it was premature to use uncompensated care costs reported on Worksheet S–10 for FY 2014. Specifically, at that time, the most recent available cost reports would have been from FYs 2010 and 2011, which were submitted on or after May 1, 2010, when the new Worksheet S–10 went into effect. We believed that "[c]oncerns about the standardization and completeness of the Worksheet S–10 data could be more acute for data collected in the first year of the Worksheet's use" (78 FR 50635). In addition, we believed that it would be most appropriate to use data elements that have been historically publicly available, subject to audit, and used for payment purposes (or that the public understands will be used for payment purposes) to determine the amount of uncompensated care for purposes of Factor 3 (78 FR 50635). At the time we issued the FY 2014 IPPS/LTCH PPS final rule, we did not believe that the available data regarding uncompensated care from Worksheet S–10 met these criteria and, therefore, we believed they were not reliable enough to use for determining FY 2014 uncompensated care payments. Accordingly, for FY 2014, we concluded that utilization of insured low-income patients would be a better proxy for the costs of hospitals in treating the uninsured. For FYs 2015, 2016, and 2017, the cost reports used for calculating uncompensated care payments (that is, FYs 2011, 2012, and 2013) were also submitted prior to the time that hospitals were on notice that Worksheet S–10 could be the data source for calculating uncompensated care payments. Therefore, we believe it is also appropriate to use proxy data to calculate Factor 3 for these years.

We believe that, for FY 2018, many of these concerns would no longer be relevant. That is, as described more fully below regarding the use of Worksheet S–10 from FY 2014, hospitals were on notice as of FY 2014 that Worksheet S–10 could eventually become the data source for CMS to calculate uncompensated care payments. Hospitals' cost reports from FY 2014 have been publically available for some time now. Furthermore, MedPAC has provided analyses that found that current Worksheet S–10 data are a better proxy for predicting audited uncompensated care costs than Medicaid/Medicare SSI days. Specifically, MedPAC submitted a public comment discussed in the FY 2016 IPPS/LTCH PPS final rule that cited its 2007 analysis of data from the Government Accountability Office (GAO) and data from the American Hospital Association (AHA), which suggests that Medicaid days and low-income Medicare days are not a good proxy for uncompensated care costs (80 FR 49525). Analysis performed by MedPAC showed that the correlation between audited uncompensated care data from 2009 and the data from FY 2011 Worksheet S–10 was over 0.80, as compared to a correlation of approximately 0.50 for 2011 Medicare SSI and Medicaid days. MedPAC concluded that use of Worksheet S–10 data was already better than using Medicare SSI and Medicaid days as a proxy for uncompensated care costs, and that the data on Worksheet S–10 would improve over time as the data are actually used to make payments.

We also have undertaken an extensive analysis of the Worksheet S–10 data, benchmarking it against the data on uncompensated care costs reported to the Internal Revenue Service (IRS) on Form 990 by not-for-profit hospitals. The purpose of this analysis, performed by Dobson DaVanzo & Associates, LLC, under contract to CMS, was to determine if Worksheet S–10 uncompensated care data are becoming more stable over time. (This analysis, included in a report entitled "Improvements to Medicare Disproportionate Share Hospital (DSH) Payments Report: Benchmarking S–10 Data Using IRS Form 990 Data and Worksheet S–10 Trend Analyses," is available on the CMS Web site at: *https://www.cms/gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html* under the Downloads section.) Although we acknowledge that the analysis was limited to not-for-profit hospitals, we believe it is relevant to our assessment of the overall quality of the data reported on Worksheet S–10. Because many not-for-profit hospitals are eligible for empirically justified Medicare DSH payments and, therefore, uncompensated care payments, they represent a suitable standard of comparison. We conducted an analysis of 2010, 2011, and 2012 Worksheet S–10 data and IRS Form 990 data from the same years. Using IRS Form 990 data for tax years 2010, 2011, and 2012 (the latest available years) as a benchmark, we compared key variables derived from Worksheet S–10 and IRS Form 990 data, such as charity care and bad debt. The analysis was completed using data from hospitals that had completed both Worksheet S–10 and IRS Form 990 across all study years, yielding a sample of 788 not-for-profit hospitals (representing 668 unique Taxpayer Identification Numbers). Because Factor 3 is used to determine the Medicare uncompensated care payment amount for each hospital, we calculated the amounts for Factor 3 for the matched hospitals using charity care and bad debt, and compared the Factor 3 distributions calculated using data from IRS Form 990 and Worksheet S–10. Key findings indicate that the amounts for Factor 3 derived using the IRS Form 990 and Worksheet S–10 data are highly correlated. In addition, the correlation coefficient between the amounts for Factor 3 calculated from the IRS Form 990 and Worksheet S–10 has increased over time, from 0.71 in 2010 to 0.80 in 2012, suggesting some convergence in the data sources over time. This strong correlation indicates that Worksheet S–10 data would be a statistically valid source to use as part of the calculation of the uncompensated care payments in FY 2018.

Accordingly, because hospitals have been on notice since the FY 2014 rulemaking that CMS intended eventually to use Worksheet S–10 as the data source for calculating uncompensated care payments, and in light of growing evidence that Worksheet S–10 data are improving over time, we believe it would be appropriate to use Worksheet S–10 as a data source for determining Factor 3 starting in FY 2018. We discuss our proposed methodology below for how we would begin to incorporate Worksheet S–10 data into the calculation of Factor 3 of the uncompensated care payment methodology.

(2) Proposed Data Source and Time Period for FY 2018 and Subsequent Years, Including Methodology for Incorporating Worksheet S–10 Data

For the reasons explained earlier, we believe that, starting with Worksheet S–10 data reported for FY 2014, it is appropriate to begin to incorporate Worksheet S–10 data into the computation of Factor 3 and the allocation of uncompensated care payments. Specifically, we are proposing to continue to use low-income insured patient days as a proxy for uncompensated care for cost reporting periods before FY 2014 and to use Worksheet S–10 data for FY 2014 and subsequent fiscal years to calculate uncompensated care payments for FY 2018 and subsequent fiscal years, which, when combined with our proposal to use data from three cost reporting periods to calculate Factor 3, would have the effect of transitioning toward exclusive use of Worksheet S–10 data. Under this proposed approach, we would use only Worksheet S–10 data to calculate Factor 3 for FY 2020 and subsequent fiscal years.

As discussed previously, for FY 2017, we are proposing to calculate a hospital's share of uncompensated care based on the proxy of its share of low-income insured days using a time period that includes three cost reports (that is, FY 2011, FY 2012, and FY 2013 cost reports). For the reasons we described earlier, we believe it would not be appropriate to use Worksheet S–10 data for periods prior to FY 2014. For cost reporting periods prior to FY 2014, we believe it would be appropriate to continue to use low-income insured days for the reasons we have previously described. Accordingly, with a time period that includes three cost reporting periods consisting of FY 2014 and two preceding periods, we are proposing to use Worksheet S–10 data for the FY 2014 cost reporting period and the low-income insured day proxy data for the two earlier cost reporting periods, drawing three sets of data from the most recently available HCRIS extract. That is, for FY 2018, to compute Factor 3, we are proposing to continue to advance the 3-year time period we are using by 1 year and therefore to use FY 2012, FY 2013, and FY 2014 cost report data from the most recent update of HCRIS. In addition, for FY 2018, we are proposing to use Medicaid days from FY 2012 and FY 2013 cost reports and FY 2014 and FY 2015 SSI ratios. We believe this approach would have a transitioning effect of incorporating data from Worksheet S–10 into the calculation of Factor 3 starting in FY 2018.

Consistent with our proposal to determine Factor 3 using data over a period of 3 cost reporting periods, we are proposing to calculate a Factor 3 for each of the three cost reporting periods. Specifically, we are proposing to calculate Factor 3 for FY 2018 based on an average of Factor 3 calculated using low-income insured days (proxy data) determined using Medicaid days from FY 2012 and FY 2013 cost reports and FY 2014 and FY 2015 SSI ratios, and Factor 3 calculated using uncompensated care data based on FY 2014 Worksheet S–10. We are proposing to compute this average for each hospital by—

- Step 1: Calculating Factor 3 using the low-income insured days proxy based on FY 2012 cost report data and the FY 2014 SSI ratio;
- Step 2: Calculating Factor 3 using the insured low-income days proxy based on FY 2013 cost report data and the FY 2015 SSI ratio;
- Step 3: Calculating Factor 3 based on the FY 2014 Worksheet S–10 data; and
- Step 4: Averaging the Factor 3 values that are computed in Steps 1, 2, and 3; that is, adding the Factor 3 values from FY 2012, FY 2013, and FY 2014 for each hospital, and dividing that amount by the number of cost reporting periods with data to compute an average Factor 3.

The denominator would be the sum of the averages of the FY 2012, FY 2013, and FY 2014 amounts from Step 4 for each hospital that is estimated to be eligible for Medicare DSH payments in FY 2018. For example, assuming there are only three hospitals in the IPPS and Hospitals A and B are estimated to be eligible for Medicare DSH payments in FY 2018, while Hospital C is estimated as ineligible for Medicare DSH payments in FY 2018, each hospital's proposed share of the overall amount available for uncompensated care payments would be calculated as follows:

[(Hospital A FY 2012 Factor 3 proxy) + (Hospital A FY 2013 Factor 3 proxy) + (Hospital A FY 2014 Factor 3 S–10)] / 3 = X

[(Hospital B FY 2012 Factor 3 proxy) + (Hospital B FY 2013 Factor 3 proxy) + (Hospital B FY 2014 Factor 3 S–10)] / 3 = Y

[(Hospital C FY 2012 Factor 3 proxy) + (Hospital C FY 2013 Factor 3 proxy) + (Hospital C FY 2014 Factor 3 S–10)] / 3 = Z

Hospital A's Factor 3 or proposed share of the overall uncompensated care amount in FY 2018 would be equal to (X) / (X+Y).

Hospital B's Factor 3 or proposed share of the overall uncompensated care amount in FY 2018 would be equal to (Y) / (X+Y).

Hospital C's Factor 3 or proposed share of the overall uncompensated care amount in FY 2018 would be equal to (Z) / (X+Y).

We note that, under this proposal, the methodology for calculating Factor 3 for each subsequent year would remain unchanged (such as using all cost reports for eligible hospitals that begin during the relevant cost reporting years, including cost reporting periods that are not 12 months in length, and using a proxy for Medicare SSI days for hospitals in Puerto Rico, as described earlier for the calculation of Factor 3 for FY 2017). With regard to FY 2019 and subsequent years, we believe it would continue to be appropriate to advance the 3-year time period we are using by 1 year to compute Factor 3. Accordingly, we are proposing to use FY 2013, FY 2014, and FY 2015 cost report data from the most recent available update of HCRIS to compute Factor 3 and allocate uncompensated care payments for FY 2019. As we stated earlier, with regard to the data used to compute Factor 3, we believe that it would be appropriate to use Worksheet S–10 data from FY 2014 and subsequent periods to calculate Factor 3 and hospitals' uncompensated care payments for FY 2018 and subsequent fiscal years. Because we are proposing to use FY 2013, FY 2014, and FY 2015 cost reports to determine Factor 3 for FY 2019, we are proposing to calculate Factor 3 with a proxy calculated based on FY 2013 cost report data and FY 2015 SSI ratios and based on Worksheet S–10 uncompensated care costs from FY 2014 and FY 2015 cost reports. We are proposing to calculate Factor 3 for FY 2019 based on an average of Factor 3 amounts calculated using data from the three cost reporting periods in the manner described earlier for FY 2018. For FY 2020, we are proposing to continue to advance the three cost reports used by 1 year, and we are proposing to calculate Factor 3 using only data from the Worksheet S–10, from cost reports from FY 2014, FY 2015, and FY 2016. For FY 2021 and subsequent fiscal years, we would continue to base our estimates of the amount of hospital uncompensated care on uncompensated care costs, using three cost reporting periods from the most recently available HCRIS database, and in each fiscal year, the cost reporting periods would be advanced forward by 1 year (for example, for FY 2021, FY 2015, FY 2016, and FY 2017 cost reports would be used). We are soliciting comments on the proposed data sources, time periods, and method for calculating uncompensated care costs in FY 2018 and subsequent years.

Although our proposal for FY 2018 is to calculate Factor 3 based on an average of the Factor 3 amounts calculated using 2 years of proxy data and 1 year of data from the FY 2014 Worksheet S–10, readers may find it useful to review a file posted on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html* under the Downloads section, which shows preliminary uncompensated care costs calculated by hospital using only Worksheet S–10 data from FY 2014 cost reports extracted from the December 2015 update of HCRIS. To the extent that hospitals have either not submitted a Worksheet S–10 with their FY 2014 cost report or find errors on a submitted Worksheet S–10, we encourage hospitals to work with MACs to complete and revise, as appropriate, their FY 2014 Worksheet S–10 as soon as possible.

(3) Proposed Definition of Uncompensated Care for FY 2018 and Subsequent Fiscal Years

In the FY 2014 IPPS/LTCH PPS rulemaking, we considered three potential definitions of uncompensated care: Charity care; charity care + bad debt; and charity care + bad debt + Medicaid shortfalls. As we explained in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50634), we considered proposing to define the amount of uncompensated care for a hospital as the uncompensated care costs of that hospital and considered potential data sources for those costs. We examined the literature on uncompensated care and the concepts of uncompensated care used in various public and private programs, and considered input from stakeholders and public comments in various forums, including the national provider call that we held in January 2013. Our review of the information from these sources indicated that there is some variation in how different States, provider organizations, and Federal programs define "uncompensated care." However, a common theme of almost all these definitions is that they include both "charity care" and "bad debt" as components of "uncompensated care." Therefore, a definition that incorporates the most commonly used factors within uncompensated care as reported by stakeholders would include charity care costs and bad debt costs. Worksheet S–10 employs the definition of charity care plus non-Medicare bad debt. Specifically:

$$\begin{array}{rr} & \text{Cost of charity care (line 23)} \\ + & \text{Cost of non-Medicare bad debt expense (line 29)} \\ \hline & \text{Cost of non-Medicare uncompensated care (line 30)} \end{array}$$

Where:

- Cost of charity care = Cost of initial obligation of patients approved for charity care (line 21) minus partial payment by patients approved for charity care (line 22).
- Cost of non-Medicare bad debt expense = Cost to charge ratio (line 1) times non-Medicare and nonreimbursable bad debt expense (line 28).

We believe a definition that incorporates the most commonly used factors within uncompensated care as reported by stakeholders would include charity care costs and non-Medicare bad debt costs which correlates to line 30 of Worksheet S–10. Therefore, we are proposing that, for purposes of calculating Factor 3 and uncompensated care costs beginning in FY 2018, "uncompensated care" would be defined as the amount on line 30 of Worksheet S–10, which is the cost of charity care and the cost of non-Medicare bad debt.

We have received many comments and questions from hospitals and hospital associations regarding whether Medicaid payment shortfalls should be included in the definition of uncompensated care. Some stakeholders argue that such payment shortfalls are unreimbursed care for low-income patients and that the definition of uncompensated care should be consistent across Medicare and Medicaid (where the longstanding Medicaid definition of uncompensated care used for Medicaid hospital-specific DSH limits includes Medicaid payment shortfalls). Proponents of including Medicare shortfalls advance two arguments:

- Medicaid payment shortfalls represent non-covered care; therefore, hospitals have unmet costs when treating these patients.
- The goal of Medicare DSH payments is to provide partial relief from charity care that is provided to (primarily) low-income patients. Because Medicaid enrollees are low-income persons, the underpayments associated with their care are a form of charity care.

In contrast, there are several arguments to support excluding Medicaid shortfalls from the definition of uncompensated care:

- Several government agencies and key stakeholders define uncompensated care as bad debt plus charity care, without consideration for Medicaid payment shortfalls. Specifically, MedPAC, GAO, and the AHA exclude Medicaid underpayments from the definition of uncompensated care.
- Including Medicaid shortfalls in the calculation of Medicare uncompensated care payments would represent a form of cross-subsidization from Medicare to cover Medicaid costs. In the past, CMS and MedPAC have not supported such action.
- Excluding Medicaid shortfalls from the uncompensated care definition allows Medicare DSH payments to better target hospitals with a disproportionate share of uncompensated care for patients with no insurance coverage.

We believe these arguments for excluding Medicare shortfalls from the definition of uncompensated care are compelling. In addition, we believe that it is advisable to adopt a definition that is used by several government agencies and key stakeholders. Therefore, we are proposing that, for purposes of calculating Factor 3 and the amount of uncompensated care for a hospital beginning in FY 2018, "uncompensated care" would be defined as the cost of charity care and the cost of non-Medicare bad debt. We also are proposing to exclude Medicaid shortfalls reported on Worksheet S–10 from the definition of uncompensated care for purposes of calculating Factor 3. We are proposing to codify this definition in the regulation at § 412.106(g)(1)(iii)(C) and are inviting public comment on our proposed definition. We believe that uncompensated care costs as reported on line 30 of Worksheet S–10 best reflect our proposed definition of uncompensated care at this time, but we welcome public input on this issue.

(4) Other Methodological Considerations for FY 2018 and Subsequent Fiscal Years

In the past several years, we also have received technical comments from stakeholders regarding the timing of reporting charity care and the CCRs used in determining uncompensated care costs. We discuss these issues and how we are proposing to incorporate them into the calculation of uncompensated care costs for purposes of determining uncompensated care payments for FY 2018 and subsequent fiscal years below.

- *Timing of Reporting Charity Care.* The determination and write-off of charity care often happens outside of the hospital fiscal year in which the services are provided. Some commenters have requested that the charity care captured on Line 20 of Worksheet S–10 include only the charity care that was written off in the particular cost reporting year, regardless of when the services were provided, consistent with charity write-offs that hospitals report in accordance with GAAP. In addition, hospitals currently report non-Medicare bad debt without regard to when the services were provided. The current Worksheet S–10 does not follow this hospital practice, and specifies that charity care provided (not necessarily written off) during the period should to be recorded on Line 20. (Instructions for Line 20 of Worksheet S–10 of the Medicare cost report CMS-Form-2552–10, "Enter the total initial payment obligation of patients who are given a full or partial discount based on the hospital's charity care criteria (measured at full charges), for care delivered *during this cost reporting period* for the entire facility . . ." (emphasis added) are included in CMS Pub. 15–2, Chapter 40, Section 4012).) While these differences in reporting should average out over time for a hospital, consistency in reporting has been requested by some stakeholders. We acknowledge these concerns, and we intend to revise the current Worksheet S–10 cost report instructions for Line 20 concerning the timing of reporting charity care, such that charity care will be reported based on date of write-off, and not based on date of service.
- *Revisions to the CCR on Line 1 of Worksheet S–10.* Many commenters have requested that the CCR used to convert charges to costs should include the cost of training residents (direct GME costs). The CCR on line 1 of Worksheet S–10 currently does not include GME costs, while the charges of teaching hospitals do include charges for GME. Thus, the CCR excludes GME costs in the cost component (or numerator), but includes GME costs in the charge component (or denominator). Commenters have requested that CMS consider using the GME costs reported in Worksheet B Part I (column 24, line 118) to capture these additional costs. Unless these GME costs are included, commenters maintained that the CCRs of teaching hospitals are artificially low, not capturing true uncompensated care costs, thereby disadvantaging teaching hospitals in the calculation of their uncompensated care costs.

Using data from FY 2011 and 2012 cost reports, we analyzed the effect on all hospitals' uncompensated care costs when GME costs are included in the numerator. Specifically, instead of calculating the CCRs as specified currently on line 1 of Worksheet S–10 (which pulls the CCR from Worksheet C, Part I, column 3, line 202/Worksheet C, column 8, line 202), we calculated the CCRs using Worksheet B, Part I, column 24, line 118/Worksheet C, Part I, column 8, line 202. As can be seen on the file posted on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html* under the Downloads section, and as expected, including GME costs in the numerator of the CCR results in an increased share of uncompensated care payments being made to teaching hospitals. Of the more than 1,000 teaching hospitals included in the analysis, the CCRs of 830 hospitals increase by less than 5 percent, 178 hospitals' CCRs increase by more than 5 percent but less than 10 percent, and 71 hospitals' CCRs increase by 10 percent or more. Thirty-three hospitals experience a decrease in their CCRs, with 32 hospitals experiencing a decrease of less than 5 percent, and 1 hospital experiencing a decrease of more than 5 percent, but less than 10 percent. As we have stated previously in response to this issue, we believe that the purpose of uncompensated care payments is to provide additional payment to hospitals for treating the uninsured, not for the costs incurred in training residents. In addition, because the CCR on line 1 of Worksheet S–10 pulled from Worksheet C, Part I, is also used in other IPPS ratesetting contexts (such as high-cost outliers and the calculation of the MS–DRG relative weights) from which it is appropriate to exclude GME because GME is paid separately from the IPPS, we hesitate to adjust the CCRs in the narrower context of calculating uncompensated care costs. Therefore, at this time, we do not believe it is appropriate to modify the calculation of the CCR on line 1 of Worksheet S–10 to include GME costs in the numerator.

- *Trims to Apply to CCRs on Line 1 of Worksheet S–10.* Commenters also have suggested that uncompensated care costs reported on Worksheet S–10 should be audited due to extremely high values consistently reported by some hospitals. We believe that, just as we apply trims to hospitals' CCRs used to calculate high-cost outlier payments to eliminate anomalies in payment determinations (§ 412.84(h)(3)(ii)), it is appropriate to apply statistical trims to the CCRs that are considered anomalies on Worksheet S–10, Line 1. Specifically, § 412.84(h)(3)(ii) states that the Medicare contractor may use a statewide CCR for hospitals whose operating or capital CCR is in excess of 3 standard deviations above the corresponding national geometric mean (that is, the CCR "ceiling"). This mean is recalculated annually by CMS and published in the proposed and final IPPS rules each year. To control for data anomalies, we are considering proposals which would trim hospitals' CCRs to ensure reasonable CCRs are used to convert charges to costs for purposes of determining uncompensated care costs.

One approach we are considering as a possible proposal for FY 2018 and subsequent years would be a "double trim" methodology as follows:

First Trim

Step 1: Prior to calculating the statewide average CCRs, all hospitals with a CCR reported on Worksheet S–10, line 1, of greater than the corresponding CCR "ceiling" (that is, the CCR "ceiling" published in the final rule of the fiscal year that is contemporaneous to the particular Worksheet S–10 data) would be removed from the calculation. We are proposing to remove the hospitals with a CCR of greater than 3 standard deviations above the corresponding national geometric mean in order to calculate the statewide average CCRs so that these aberrant CCRs do not skew the statewide average CCR.

Step 2: Using the CCRs for the remaining hospitals in Step 1, determine the statewide average CCRs using line 1 of Worksheet S–10 for hospitals within each State (including non-DSH eligible hospitals).

Step 3: Calculate the simple average CCR (not weighted by hospital size) for each State.

Step 4: First CCR Trim—Assign the statewide average CCR calculated in Step 3 to all hospitals with a CCR greater than 3 standard deviations above the corresponding national geometric mean (that is, the CCR "ceiling").

Second Trim

Step 5: Calculate the natural logarithm of the CCR for all hospitals (including those with replaced CCRs and those not eligible for Medicare DSH payments).

Step 6: Calculate the geometric mean and standard deviation of the log values across all hospitals (including those not eligible for Medicare DSH payments).

Step 7: Second CCR Trim—Assign the statewide average CCR calculated in Step 3 to each Medicare DSH eligible hospital with a CCR greater than 3.0 standard deviations above the geometric mean. All hospitals not eligible for Medicare DSH payments should be excluded from further analyses.

Analysis we performed under this "double trim" approach was based on CCRs from FY 2012 Worksheet S–10, Line 1. Under Step 1, we used the FY 2013 CCR "ceiling" of 1.146 published in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53697). (We used the FY 2013 CCR "ceiling" because it was computed from the March 2012 update of the Provider Specific File, which contained CCRs that are relatively contemporaneous to the CCRs in the FY 2012 cost reports.) Our analysis shows that 27 hospitals would receive their respective statewide average CCR. (We refer readers to our analysis posted on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Servie-Payment/AcuteInpatientPPS/dsh.html* under the Downloads section.)

Alternatively, we are considering proposing for FY 2018 and subsequent years to use the same trim process that is used for high-cost outliers under § 412.84(i), under which we calculate separate urban and rural average CCRs for each state. Thus, the CCR of an urban or rural hospital above the applicable CCR "ceiling" for a given fiscal year would be replaced by its respective urban or rural statewide average CCR. As a reference, the FY 2013 IPPS statewide average urban and rural CCRs are in Table 8A included on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download-Items/FY2013-FinalRule-CorrectionNotice-Files.html.*

After applying the applicable trims to a hospital's CCR as appropriate, we would calculate a hospital's uncompensated care costs as being equal to line 30, which is the sum of line 23 and line 29, as follows:

Hospital Uncompensated Care Costs = line 30 (=line 23 + line 29), which is equal to—

[(Line 1 CCR *adjusted by trim if applicable* × charity care line 20) − (Payments received for charity care line 22)]

+

[(Line 1 CCR *adjusted by trim if applicable* × Non-Medicare and non-reimbursable Bad Debt line 28)].

We are inviting public comments on these methodological considerations.

G. Hospital Readmissions Reduction Program: Proposed Updates and Changes (§§ 412.150 Through 412.154)

1. Statutory Basis for the Hospital Readmissions Reduction Program

Section 3025 of the Affordable Care Act, as amended by section 10309 of the Affordable Care Act, added section 1886(q) to the Act, which establishes the "Hospital Readmissions Reduction Program" effective for discharges from "applicable hospitals" beginning on or after October 1, 2012. Under the Hospital Readmissions Reduction Program, payments to applicable hospitals may be reduced to account for certain excess readmissions. We refer readers to section IV.E.1. of the FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49531) for a detailed discussion and additional information on of the statutory history of the Hospital Readmissions Reduction Program.

2. Regulatory Background

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51660 through 51676), we addressed the issues of the selection of readmission measures and the calculation of the excess readmissions ratio, which will be used, in part, to calculate the readmissions adjustment factor. Specifically, in that final rule, we finalized policies that relate to the portions of section 1886(q) of the Act that address the selection of and measures for the applicable conditions, the definitions of "readmission" and "applicable period," and the methodology for calculating the excess readmissions ratio. We also established policies with respect to measures for readmission for the applicable conditions and our methodology for calculating the excess readmissions ratio.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53374 through 53401), we finalized policies that relate to the portions of section 1886(q) of the Act that address the calculation of the hospital readmission payment adjustment factor and the process by which hospitals can review and correct their data. Specifically, in that final rule, we addressed the base operating DRG payment amount, aggregate payments for excess readmissions and aggregate payments for all discharges, the adjustment factor, applicable hospital, limitations on review, and reporting of hospital-specific information, including the process for hospitals to review readmission information and submit corrections. We also established a new Subpart I under 42 CFR part 412 (§§ 412.150 through 412.154) to codify rules for implementing the Hospital Readmissions Reduction Program.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50649 through 50676), we finalized our policies that relate to refinement of the readmissions measures and related methodology for the current applicable conditions, expansion of the "applicable conditions" for FY 2015 and subsequent fiscal years, and clarification of the process for reporting hospital-specific information, including the opportunity to review and submit corrections. We also established policies related to the calculation of the adjustment factor for FY 2014.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50024 through 50048), we made refinements to the readmissions measures and related methodology for applicable conditions for FY 2015 and subsequent fiscal years, discussed the maintenance of technical specifications for quality measures, and described a waiver from the Hospital Readmissions Reduction Program for hospitals formerly paid under section 1814(b)(3) of the Act (§ 412.154(d)). We also specified the "applicable period" for FY 2015 and made changes to the calculation of the aggregate payments for excess readmissions so as to include two additional applicable conditions for the FY 2015 payment determination. Finally, we expanded the list of applicable conditions for the FY 2017 payment determination to include the Hospital-Level, 30-Day, All-Cause, Unplanned Readmission Following Coronary Artery Bypass Graft (CABG) Surgery measure.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49543), we made a refinement to the pneumonia readmissions measure that expanded the measure cohort for the FY 2017 payment determination and subsequent years (80 FR 49532 through 49536); adopted an extraordinary circumstance exception policy to address hospitals that experience a disaster or other extraordinary circumstance beginning in FY 2016 and for subsequent years (80 FR 49542 through 49543); specified the adjustment factor floor for FY 2016 (80 FR 49537); and specified the calculation of aggregate payments for excess readmissions for FY 2016 (80 FR 49537 through 49542).

3. Proposed Policies for the FY 2017 Hospital Readmissions Reduction Program

In this proposed rule, we are proposing to—

- Clarify that public reporting of excess readmission ratios will be posted on an annual basis to the *Hospital Compare* Web site as soon as is feasible following the preview period.
- Discuss the proposed methodology to include the addition of the CABG applicable condition in the calculation of the readmissions payment adjustment for FY 2017.

4. Maintenance of Technical Specifications for Quality Measures

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50039) for a discussion of the maintenance of technical specifications for quality measures for the Hospital Readmissions Reduction Program. Technical specifications of the readmission measures are provided on our Web site in the Measure Methodology Reports at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.* Additional resources about the Hospital Readmissions Reduction Program and measure technical specifications are on the QualityNet Web site on the Resources page at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772412995.*

We want to remind readers that, in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49532), we discussed our policies regarding the use of sociodemographic factors in quality measures. We understand the important role that sociodemographic status plays in the care of patients. However, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on hospitals' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are encouraged to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

5. Proposed Applicable Period for FY 2017

Under section 1886(q)(5)(D) of the Act, the Secretary has the authority to specify the applicable period with respect to a fiscal year under the Hospital Readmissions Reduction Program. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51671), we finalized our policy to use 3 years of claims data to calculate the readmission measures. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53675), we codified the definition of "applicable period" in the regulations at 42 CFR 412.152 as the 3-year period from which data are collected in order to calculate excess readmissions ratios and adjustments for the fiscal year, which includes aggregate payments for excess readmissions and aggregate payments for all discharges used in the calculation of the payment adjustment.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49537), for FY 2016, consistent with the definition specified at § 412.152, we established an "applicable period" for the Hospital Readmissions Reduction Program of the 3-year period from July 1, 2011 through June 30, 2014. In other words, the excess readmissions ratios and the payment adjustment (including aggregate payments for excess readmissions and aggregate payments for all discharges) for FY 2016 were determined using data from the 3-year time period of July 1, 2011 through June 30, 2014.

In this proposed rule, for FY 2017, consistent with the definition specified at § 412.152, we are proposing that the "applicable period" for the Hospital Readmissions Reduction Program will be the 3-year period from July 1, 2012 through June 30, 2015. In other words, we are proposing that the excess readmissions ratios and the payment adjustment (including aggregate payments for excess readmissions and aggregate payments for all discharges) for FY 2017 would be calculated using data from the 3-year time period of July 1, 2012 through June 30, 2015.

6. Proposed Calculation of Aggregate Payments for Excess Readmissions for FY 2017

Section 1886(q)(3)(B) of the Act specifies the ratio used to calculate the adjustment factor under the Hospital Readmissions Reduction Program. It states that the ratio is equal to 1 minus the ratio of—(i) The aggregate payments for excess readmissions and (ii) the aggregate payments for all discharges. The definition of "aggregate payments for excess readmissions" and "aggregate payments for all discharges," as well as a methodology for calculating the numerator of the ratio (aggregate payments for excess readmissions) and the denominator of the ratio (aggregate payments for all discharges) are codified at § 412.154(c)(2).

Section 1886(q)(4) of the Act sets forth the definitions of "aggregate payments for excess readmissions" and "aggregate payments for all discharges" for an applicable hospital for the applicable period. The term "aggregate payments for excess readmissions" is defined in section 1886(q)(4)(A) of the Act and § 412.152 of our regulations as, for a hospital for an applicable period, the sum, for applicable conditions of the product, for each applicable condition, of: (i) The base operating DRG payment amount for such hospital for such applicable period for such condition; (ii) the number of admissions for such condition for such hospital for such applicable period; and (iii) the excess readmissions ratio for such hospital for such applicable period minus 1.

The excess readmissions ratio is a hospital-specific ratio calculated for each applicable condition. Specifically, section 1886(q)(4)(C) of the Act defines the excess readmissions ratio as the ratio of "risk-adjusted readmissions based on actual readmissions" for an applicable hospital for each applicable condition, to the "risk-adjusted expected readmissions" for the applicable hospital for the applicable condition. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51673) for additional information on the methodology for the calculation of the excess readmissions ratio. "Aggregate payments for excess readmissions" is the numerator of the ratio used to calculate the adjustment factor under the Hospital Readmissions Reduction Program.

The term "aggregate payments for all discharges" is defined at section 1886(q)(4)(B) of the Act as for a hospital for an applicable period, the sum of the base operating DRG payment amounts for all discharges for all conditions from such hospital for such applicable period. We codified this definition of "aggregate payments for all discharges" under the regulations at § 412.152. "Aggregate payments for all discharges" is the denominator of the ratio used to calculate the adjustment factor under the Hospital Readmissions Reduction Program.

The Hospital Readmissions Reduction Program currently includes the following five applicable conditions: acute myocardial infarction (AMI), heart failure (HF), pneumonia (PN), total hip arthroplasty/total knee arthroplasty (THA/TKA), and chronic obstructive pulmonary disease (COPD). In the FY 2015 IPPS/LTCH PPS final rule effective for FY 2017 (79 FR 50033 through 50039), we finalized the inclusion of an additional applicable condition, Hospital-Level, 30-Day, All-Cause, Unplanned Readmission Following Coronary Artery Bypass Graft (CABG) Surgery.

In this section, we discuss the proposed methodology to include this additional measure in the calculation of the readmissions payment adjustment for FY 2017. Specifically, we are proposing how the addition of CABG applicable conditions would be included in the calculation of the aggregate payments for excess readmissions (the numerator of the readmissions payment adjustment). We note that this proposal does not alter our established methodology for calculating aggregate payments for all discharges; that is, the denominator of the ratio.

When calculating the numerator (aggregate payments for excess readmissions), we determine the base operating DRG payments for the applicable period. "Aggregate payments for excess readmissions" (the numerator) is defined as the sum, for applicable conditions, of the product, for each applicable condition, of: (i) The base operating DRG payment amount for such hospital for such applicable period for such condition; (ii) the number of admissions for such condition for such hospital for such applicable period; and (iii) the excess readmissions ratio for such hospital for such applicable period minus 1.

When determining the base operating DRG payment amount for an individual hospital for such applicable period for such condition, we use Medicare inpatient claims from the MedPAR file with discharge dates that are within the same applicable period to calculate the excess readmissions ratio. We use MedPAR claims data as our data source for determining aggregate payments for excess readmissions and aggregate payments for all discharges, as this data source is consistent with the claims data source used in IPPS rulemaking to determine IPPS rates.

For FY 2017, we are proposing to use MedPAR claims with discharge dates that are on or after July 1, 2012, and no later than June 30, 2015, consistent with our historical use of a 3-year applicable period. Under our established methodology, we use the update of the MedPAR file for each Federal fiscal year, which is updated 6 months after the end of each Federal fiscal year within the applicable period, as our data source (that is, the March updates of the respective Federal fiscal year MedPAR files) for the final rules.

The FY 2012 through FY 2015 MedPAR data files can be purchased from CMS. Use of these files allows the public to verify the readmissions adjustment factors. Interested individuals may order these files through the CMS Web site at: *http://www.cms.hhs.gov/LimitedDataSets/* by clicking on MedPAR Limited Data Set (LDS)-Hospital (National). This Web page describes the files and provides directions and detailed instructions for how to order the data sets.

In this proposed rule, for FY 2017, we are proposing to determine aggregate payments for excess readmissions and aggregate payments for all discharges using data from MedPAR claims with discharge dates that are on or after July 1, 2012, and no later than June 30, 2015. However, we note that, for the purpose of modeling the proposed FY 2017 readmissions payment adjustment factors for this proposed rule, we use excess readmissions ratios for applicable hospitals from the FY 2016 Hospital Readmissions Reduction Program applicable period. For the FY 2017 final rule, applicable hospitals will have had the opportunity to review and correct data from the proposed FY 2017 applicable period of July 1, 2012 to June 30, 2015, before they are made public under our policy regarding the preview and reporting of hospital-specific information, which we discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53374 through 53401).

In this proposed rule, for FY 2017, we are proposing to use MedPAR data from July 1, 2012 through June 30, 2015. Specifically, for this proposed rule, we are using the March 2013 update of the FY 2012 MedPAR file to identify claims within FY 2012 with discharges dates that are on or after July 1, 2012, the March 2014 update of the FY 2013 MedPAR file to identify claims within FY 2013, the March 2015 update of the FY 2014 MedPAR file to identify claims within FY 2014, and the December 2015 update of the FY 2015 MedPAR file to identify claims within FY 2015 with discharge dates no later than June 30, 2015. For the final rule, we are proposing to use the same MedPAR files as listed above for claims within FY 2012, FY 2013 and FY 2014, and for claims within FY 2015, we are proposing to use the March 2016 update of the FY 2015 MedPAR file.

For a discussion of how we identified the applicable conditions to calculate the aggregate payments for excess readmissions for FY 2016, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49538 through 49541). For FY 2017, with the addition of the CABG measure to the applicable conditions under the Hospital Readmissions Reduction Program, we are proposing to follow this same approach.

In this proposed rule, for FY 2017, we are proposing to continue to apply the same exclusions to the claims in the MedPAR file as we applied for FY 2016 for the AMI, HF, PN, THA/TKA, and COPD applicable conditions. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49539) for a list of these exclusions. Updates to these exclusions will be posted on the QualityNet Web site at: *http://www.QualityNet.org* > Hospital-Inpatient > Claims-Based Measures > Readmission Measures > Measure Methodology.

In addition to the exclusions described above, for FY 2017, we are proposing the following steps to identify admissions specifically for CABG for the purposes of calculating aggregate payments for excess readmissions. These exclusions were previously finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50037):

- Admissions for patients who are discharged against medical advice (excluded because providers do not have the opportunity to deliver full care and prepare the patient for discharge);
- Admissions for patients who die during the initial hospitalization (these patients are not eligible for readmission);
- Admissions for patients with subsequent qualifying CABG procedures during the measurement period (a repeat CABG procedure during the measurement period very likely represents a complication of the original CABG procedure and is a clinically more complex and higher risk surgery; therefore, we select the first CABG admission for inclusion in the measure and exclude subsequent CABG admissions from the cohort); and
- Admissions for patients without at least 30 days post-discharge enrollment in Medicare FFS (excluded because the

30-day readmission outcome cannot be assessed in this group).

As noted previously, these exclusions are consistent with our current methodology, and any updates to these exclusions will be posted on the QualityNet Web site at: *http://www.QualityNet.org* > Hospital-Inpatient > Claims-Based Measures > Readmission Measures > Measure Methodology.

Furthermore, we would only identify Medicare FFS claims that meet the criteria (that is, claims paid for under Medicare Part C, Medicare Advantage, would not be included in this calculation), consistent with the methodology to calculate excess readmissions ratios based solely on admissions and readmissions for Medicare FFS patients. Therefore, consistent with our established methodology, for FY 2017, we would exclude admissions for patients enrolled in Medicare Advantage as identified in the Medicare Enrollment Database. This policy is consistent with how admissions for Medicare Advantage patients are identified in the calculation of the excess readmissions ratios under our established methodology.

In order to identify the admissions for each applicable condition for FY 2017 to calculate the aggregate payments for excess readmissions for an individual hospital, we are proposing to identify each applicable condition, including the CABG condition, using the appropriate ICD–9–CM codes. (Although the compliance date for the ICD–10–CM and ICD–10–PCS code sets was October 1, 2015, these proposed policies apply to data submitted prior to this compliance date.) Under our existing policy, we identify eligible hospitalizations and readmissions of Medicare patients discharged from an applicable hospital having a principal diagnosis for the measured condition in an applicable period (76 FR 51669). The discharge diagnoses for each applicable condition are based on a list of specific ICD–9–CM codes for that condition. The ICD–9–CM codes for the AMI, HF, PN, THA/TKA, COPD, and CABG applicable conditions can be found on the QualityNet Web site at: *http://www.QualityNet.org* > Hospital-Inpatient > Claims-Based Measures > Readmission Measures > Measure Methodology. Consistent with our established policy (76 FR 51673 through 51676), we are proposing to use the ICD–9–CM codes to identify the applicable conditions in calculation of the excess readmissions ratios, which are provided in the measure methodology reports on the QualityNet Web site, to identify each applicable condition to calculate the aggregate payments for the excess readmissions ratios for FY 2017. For a complete list of the ICD–9–CM codes we are proposing to use to identify the applicable conditions, we refer readers to the following tables of those reports:

- 2015 Measure Updates: AMI, HF, Pneumonia, COPD, Stroke Readmission (*AMI-Version 8.0, HF-Version 8.0, Pneumonia-Version 8.0, COPD-Version 4.0, and Stroke-Version 4.0: 2015 Condition-Specific Readmission Measures Updates and Specifications Report*)—
  - ++ Table D.1.1—ICD–9–CM Codes for AMI Cohort (page 74).
  - ++ Table D.2.1—ICD–9–CM Codes for HF Cohort (page 78).
  - ++ Table D.3.1—ICD–9–CM Codes for Pneumonia Cohort (page 82).
  - ++ Table D.4.1—ICD–9–CM Codes for COPD Cohort (page 87).
- 2015 Measure Updates: THA/TKA and CABG Readmission (*THA and/or TKA-Version 4.0, CABG-Version 2.0: 2015 Procedure-Specific Readmission Measures Updates and Specifications Report,*)—
  - ++ Table D.1.1—ICD–9–CM Codes Used to Identify Eligible THA/TKA Procedures (page 45).
  - ++ Table D.2.1—ICD–9–CM Codes Used to Identify Eligible CABG Procedures (page 53).

For FY 2017, we are proposing to calculate aggregate payments for excess readmissions, using MedPAR claims from July 1, 2012 to June 30, 2015, to identify applicable conditions based on the same ICD–9–CM codes used to identify the conditions for the readmissions measures, and to apply the proposed exclusions for the types of admissions (as previously discussed). To calculate aggregate payments for excess readmissions for each hospital, we are proposing to calculate the base operating DRG payment amounts for all claims in the 3-year applicable period for each applicable condition (AMI, HF, PN, COPD, THA/TKA, and CABG) based on the claims we have identified as described above. Once we have calculated the base operating DRG amounts for all the claims for the six applicable conditions, we are proposing to sum the base operating DRG payments amounts by each condition, resulting in six summed amounts, one amount for each of the six applicable conditions. We are proposing to then multiply the amount for each condition by the respective excess readmissions ratio minus 1 when that excess readmissions ratio is greater than 1, which indicates that a hospital has performed, with respect to readmissions for that applicable condition, worse than the average hospital with similar patients. Each product in this computation represents the payments for excess readmissions for that condition. We are proposing to then sum the resulting products which represent a hospital's proposed "aggregate payments for excess readmissions" (the numerator of the ratio). Because this calculation is performed separately for each of the six conditions, a hospital's excess readmissions ratio must be less than or equal to 1 on each measure to avoid CMS' determination that there were payments made by CMS for excess readmissions (resulting in a payment reduction under the Hospital Readmissions Reduction Program). In other words, in order to avoid a payment reduction a hospital's excess readmissions ratio must be less than or equal to 1 on each measure. We note that we are not proposing any changes to our existing methodology to calculate "aggregate payments for all discharges" (the denominator of the ratio).

Section 1886(q)(3)(A) of the Act defines the "adjustment factor" for an applicable hospital for a fiscal year as equal to the greater of (i) The ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or (ii) the floor adjustment factor specified in subparagraph (C). Section 1886(q)(3)(B) of the Act, in turn, describes the ratio used to calculate the adjustment factor. Specifically, it states that the ratio is equal to 1 minus the ratio of—(i) the aggregate payments for excess readmissions and (ii) the aggregate payments for all discharges. The calculation of this ratio is codified at § 412.154(c)(1) of the regulations and the floor adjustment factor is codified at § 412.154(c)(2) of the regulations. Section 1886(q)(3)(C) of the Act specifies the floor adjustment factor at 0.97 for FY 2015 and subsequent fiscal years.

Consistent with section 1886(q)(3) of the Act, codified at § 412.154(c)(2), for FY 2017, the adjustment factor is either the greater of the ratio or the floor adjustment factor of 0.97. Under our established policy, the ratio is rounded to the fourth decimal place. In other words, for FY 2017, a hospital subject to the Hospital Readmissions Reduction Program will have an adjustment factor that is between 1.0 (no reduction) and 0.9700 (greatest possible reduction).

We are proposing the following methodology for FY 2017 as displayed in the chart below.

FORMULAS TO CALCULATE THE READMISSIONS ADJUSTMENT FACTOR FOR FY 2017

Aggregate payments for excess readmissions = [sum of base operating DRG payments for AMI x (Excess Readmissions Ratio for AMI–1)] + [sum of base operating DRG payments for HF x (Excess Readmissions Ratio for HF–1)] + [sum of base operating DRG payments for PN x (Excess Readmissions Ratio for PN–1)] + [sum of base operating DRG payments for COPD) x (Excess Readmissions Ratio for COPD–1)] + [sum of base operating DRG payments for THA/TKA x (Excess Readmissions Ratio for THA/TKA–1)] + [sum of base operating DRG payments for CABG x (Excess Readmissions Ratio for CABG–1)].

*We note that if a hospital's excess readmissions ratio for a condition is less than/equal to 1, there are no aggregate payments for excess readmissions for that condition included in this calculation.

Aggregate payments for all discharges = sum of base operating DRG payments for all discharges.

Ratio = 1 − (Aggregate payments for excess readmissions/Aggregate payments for all discharges).

Proposed Readmissions Adjustment Factor for FY 2017 is the higher of the ratio or 0.9700.

*Based on claims data from July 1, 2012 to June 30, 2015 for FY 2017.

We are inviting public comment on these proposals.

7. Extraordinary Circumstance Exception Policy

We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49542 through 49543) for a detailed discussion of our Extraordinary Circumstance Exception policy for the Hospital Readmissions Reduction Program.

During the review of a hospital's request for an extraordinary circumstance exception, we maintain the general principle that providing high quality of care and ensuring patient safety is of paramount importance. We intend to provide relief only for hospitals whose ability to accurately or timely submit all of their claims (from which readmission measures data are derived) has been negatively impacted as a direct result of experiencing a significant disaster or other extraordinary circumstance beyond the control of the hospital. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49542 through 49543) we finalized that the request process for an extraordinary circumstance exception begins with the submission of an extraordinary circumstance exception request form by a hospital within 90 calendar days of the natural disaster or other extraordinary circumstance. Under this policy, a hospital is able to request a Hospital Readmissions Reduction Program extraordinary circumstance exception at the same time it may request a similar exception under the Hospital IQR Program, the Hospital VBP Program, and the HAC Reduction Program. The extraordinary circumstance exception request form is available on the QualityNet Web site.

The following information is required to submit the request:

- Hospital CCN;
- Hospital name;
- Hospital Chief Executive Officer (CEO) and any other designated personnel contact information, including name, email address, telephone number, and mailing address (must include a physical address; a post office box address is not acceptable);
- Hospital's reason for requesting an exception, including:
    ++ CMS program name (for example, the Hospital Readmissions Reduction Program, the Hospital VBP Program, or the Hospital IQR Program);
    ++ The measure(s) and submission quarters affected by the extraordinary circumstance that the hospital is seeking an exception for should be accompanied with the specific reasons why the exception is being sought; and
    ++ How the extraordinary circumstance negatively impacted performance on the measure(s) for which an exception is being sought;
- Evidence of the impact of the extraordinary circumstances, including but not limited to, photographs, newspaper, and other media articles; and
- The request form must be signed by the hospital's CEO or designated non-CEO contact and submitted to CMS.

The same set of information is currently required under the Hospital IQR Program and the Hospital VBP Program on the request form from a hospital seeking an extraordinary circumstance exception with respect to these programs. The specific list of required information is subject to change from time to time at the discretion of CMS.

Following receipt of the request form, CMS will: (1) Provide a written acknowledgement of receipt of the request using the contact information provided in the request form to the CEO and any additional designated hospital personnel; and (2) provide a formal response to the CEO and any additional designated hospital personnel using the contact information provided in the request notifying them of our decision. We review each request for an extraordinary circumstance exception on a case-by-case basis at our discretion. To the extent feasible, we also review requests in conjunction with any similar requests made under other IPPS quality reporting and payment programs, such as the Hospital IQR Program and the Hospital VBP Program.

This policy does not preclude CMS from granting extraordinary circumstance exceptions to hospitals that do not request them if we determine at our discretion that a disaster or other extraordinary circumstance has affected an entire region or locale. If CMS makes such a determination to grant an extraordinary circumstance exception to hospitals in an affected region or locale, we would convey this decision through routine communication channels to hospitals, vendors, and QIOs, including, but not limited to, issuing memos, emails, and notices on the QualityNet Web site. This provision aligns with the Hospital IQR Program's extraordinary circumstances extensions or exemptions policy.

8. Timeline for Public Reporting of Excess Readmission Ratios on *Hospital Compare* for the FY 2017 Payment Determination

Section 1886(q)(6) of the Act requires the Secretary to make information available to the public regarding readmission rates of each subsection (d) hospital under the program, and states that such information shall be posted on the *Hospital Compare* Internet Web site in an easily understandable format. Accordingly, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53401), we indicated that public reporting for excess readmission ratios could be available on the *Hospital Compare* Web site as early as mid-October. In this proposed rule, we are clarifying that public reporting of excess readmission ratios will be posted on an annual basis to the *Hospital Compare* Web site as soon as is feasible following the review period. This may occur as early as October, but it could occur later for a particular year in order to streamline reporting and align with other hospital quality reporting and performance programs.

H. Hospital Value-Based Purchasing (VBP) Program: Proposed Policy Changes for the FY 2018 Program Year and Subsequent Years

1. Background

a. Statutory Background and Overview of Past Program Years

Section 1886(o) of the Act, as added by section 3001(a)(1) of the Affordable Care Act, requires the Secretary to establish a hospital value-based purchasing program (the Hospital VBP Program) under which value-based incentive payments are made in a fiscal year to hospitals that meet performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary.

For more of the statutory background and descriptions of our current policies for the Hospital VBP Program, we refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26490 through 26547); the FY 2012 IPPS/LTCH PPS final rule (76 FR 51653 through 51660); the CY 2012 OPPS/ASC final rule with comment period (76 FR 74527 through 74547); the FY 2013 IPPS/LTCH PPS final rule (77 FR 53567 through 53614); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50676 through 50707); the CY 2014 OPPS/ASC final rule (78 FR 75120 through 75121); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50048 through 50087); and the FY 2016 IPPS/LTCH PPS final rule with comment period (80 FR 49544 through 49570).

We also have codified certain requirements for the Hospital VBP Program at 42 CFR 412.160 through 412.167.

b. FY 2017 Program Year Payment Details

Section 1886(o)(7)(B) of the Act instructs the Secretary to reduce the base operating DRG payment amount for a hospital for each discharge in a fiscal year by an applicable percent. Under section 1886(o)(7)(A) of the Act, the sum total of these reductions in a fiscal year must equal the total amount available for value-based incentive payments for all eligible hospitals for the fiscal year, as estimated by the Secretary. We finalized details on how we would implement these provisions in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573) and refer readers to that rule for further details.

Under section 1886(o)(7)(C)(iv) of the Act, the applicable percent for the FY 2017 program year is 2.00 percent. Using the methodology we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573), we estimate that the total amount available for value-based incentive payments for FY 2017 is approximately $1.7 billion, based on the December 2015 update of the FY 2015 MedPAR file. We intend to update this estimate for the FY 2017 IPPS/LTCH PPS final rule, using the March 2016 update of the FY 2015 MedPAR file.

As finalized in the FY 2013 IPPS/LTCH PPS final rule, we will utilize a linear exchange function to translate this estimated amount available into a value-based incentive payment percentage for each hospital, based on its Total Performance Score (TPS) (77 FR 53573 through 53576). We will then calculate a value-based incentive payment adjustment factor that will be applied to the base operating DRG payment amount for each discharge occurring in FY 2017, on a per-claim basis. We are publishing proxy value-based incentive payment adjustment factors in Table 16 associated with this proposed rule (which is available via the Internet on the CMS Web site). The proxy factors are based on the TPSs from the FY 2016 program year. These FY 2016 performance scores are the most recently available performance scores that hospitals have been given the opportunity to review and correct. The slope of the linear exchange function used to calculate those proxy value-based incentive payment adjustment factors is 2.7714997322. This slope, along with the estimated amount available for value-based incentive payments, is also published in Table 16.

We intend to update this table as Table 16A in the final rule (which will be available via the Internet on the CMS Web site) to reflect changes based on the March 2016 update to the FY 2015 MedPAR file. We also intend to update the slope of the linear exchange function used to calculate those updated proxy value-based incentive payment adjustment factors. The updated proxy value-based incentive payment adjustment factors for FY 2017 will continue to be based on historic FY 2016 program year TPSs because hospitals will not have been given the opportunity to review and correct their actual TPSs for the FY 2017 program year until after the FY 2017 IPPS/LTCH PPS final rule is published. After hospitals have been given an opportunity to review and correct their actual TPSs for FY 2017, we will add Table 16B (which will be available via the Internet on the CMS Web site) to display the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount available for the FY 2017 program year. We expect that Table 16B will be posted on the CMS Web site in October 2016.

2. PSI 90 Measure in the FY 2018 Program and Future Program Years

a. Proposed PSI 90 Measure Performance Period Change for the FY 2018 Program Year

We previously finalized the performance period for the PSI 90: Patient Safety for Selected Indicators (Composite Measure) (then referred to as both the "PSI–90 measure" and the "AHRQ PSI Composite Measure") for the FY 2018 program year (78 FR 50694). We have calculated and finalized performance standards for the FY 2018 program year based on a baseline period that uses ICD–9–CM claims data. The previously finalized performance period for the FY 2018 program year runs from July 1, 2014 through June 30, 2016. Because hospitals began ICD–10–CM/PCS implementation on October 1, 2015, the performance period as currently finalized for the FY 2018 program year would necessitate using both ICD–9 and ICD–10 claims data to calculate performance standards for the PSI 90 measure.

Since the ICD–10 transition was implemented on October 1, 2015, we have been monitoring our systems, and claims are processing normally. Currently, the measure steward, AHRQ, is reviewing any potential issues related to ICD–10 conversion of coded operating room procedures (*https://www.cms.gov/icd10manual/fullcode_cms/P1616.html*), which directly impact the AHRQ PSI 90 component indicators. Nevertheless, given the complexity of converting the PSI 90 component indicators from ICD–9 to ICD–10 and considering that there are approximately 70,000 [22] ICD–10 codes, the measure steward has recommended against combining measure performance data that use both ICD–9 and ICD–10 data at this time. In addition, to meet program requirements and implementation schedules, our system requires an ICD–10 risk-adjusted version of the AHRQ QI PSI software [23] by December 2016 for use in the FY 2018 payment year. At this time, a risk adjusted ICD–10 version of the PSI 90 software is not expected to be available until late CY 2017.

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[22] International Classification of Diseases (ICD–10–CM/PCS) Transition—Background. Available at: *http://www.cdc.gov/nchs/icd/icd10cm_pcs_background.htm.*

[23] The AHRQ QI Software is the software used to calculate PSIs and the composite measure. More information is available at: *http://www.qualityindicators.ahrq.gov/Downloads/Resources/Publications/2015/Empirical_Methods_2015.pdf.*

To address the above issues, we are proposing to shorten the performance period for the FY 2018 program year. We are proposing to use a 15-month performance period from July 1, 2014 through September 30, 2015 for the FY 2018 program year. The 15-month performance period would only apply to the FY 2018 program year and would only use ICD–9 data. For the FY 2018 program year, the performance standards that were previously established and announced in past rules would not change because they were calculated based on the baseline period of July 1, 2010 through June 30, 2012, which would remain the same. In order to align the use of this measure with other hospital quality programs, we are proposing similar modifications to the FY 2018 reporting period for the PSI 90 measure for the HAC Reduction Program, as set forth in section IV.I. of the preamble of this proposed rule, and for the Hospital IQR Program, as set forth in section VIII.A. of the preamble of this proposed rule.

We are aware that the FY 2019 program year also has a performance period that contains ICD–9 and ICD–10 data (79 FR 50072 through 50073). We will continue to review our options for calculating the performance period for the FY 2019 program year and further address this in next year's rulemaking. Therefore, we are not proposing to make any changes to the FY 2019 program year, which runs from July 1, 2015 through June 30, 2017.

We note that in proposing a shortened performance period for the PSI 90 measure, a prior reliability analysis of the PSI 90 measure shows that the majority of hospitals attain a moderate or high level of reliability for the PSI 90 measure after a 12-month period.[24] We do not anticipate any delay for hospitals to review their TPS for the FY 2018 program year during the review and correction period.

Prior to deciding to propose an abbreviated performance period for the FY 2018 program year, we took several factors into consideration, including the recommendations of the measure steward, the feasibility of using a combination of ICD–9 and ICD–10 data without the availability of the appropriate measure software, minimizing provider burden, program implementation timelines, and the reliability of using shortened performance periods, as well as the importance of continuing to publicly report this measure. We believe that using a 15-month performance period for FY 2018 best serves the need to provide important information on hospital patient safety and adverse events by allowing sufficient time to process the claims data and calculate the measures, while minimizing the reporting burden and program disruption.

Furthermore, we plan to propose to adopt the modified PSI 90 measure, which includes several substantive measure updates, for the Hospital VBP Program in subsequent rulemaking, as soon as it is feasible. We discuss this future proposed adoption in section IV.H.2.b. of the preamble of this proposed rule.

We are inviting public comments on this proposed plan to shorten the performance period for the PSI 90 measure for the FY 2018 program year.

b. Intent To Propose in Future Rulemaking To Adopt the Modified PSI 90 Measure

The PSI 90 measure underwent NQF maintenance review in 2014. The 2014 NQF maintenance review process has been completed and has led to several changes to the measure.[25] Due to statutory requirements[26] in the Hospital VBP Program, we would not be able to adopt the NQF-endorsed modified PSI 90 measure, now known as Patient Safety and Adverse Events Composite, until a future program year. We refer readers to section VIII.A. of the preamble of this proposed rule relating to the Hospital IQR Program for a discussion of the modified PSI 90 measure update.

3. Retention Policy, Domain Name Proposal, and Updating of Quality Measures for the FY 2019 Program Year

a. Retention of Previously Adopted Hospital VBP Program Measures

Since the FY 2013 IPPS/LTCH PPS final rule (77 FR 53592), we have retained measures from prior program years for each successive program year, unless otherwise proposed and finalized. We are not proposing any changes to this policy.

b. Proposed Domain Name Change

We strive to align quality measurement and value-based purchasing programs with the NQS priority and the CMS Quality Strategy. Value-based purchasing programs in particular allow us to link the CMS Quality Strategy with Medicare payments to providers and suppliers on a national scale. Given this objective, as well as our objective to focus quality measurement on the patient-centered outcome of interest to the extent possible, we proposed to reclassify the Hospital VBP Program measures into domains based on the six priorities of the CMS Quality Strategy. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50702), we proposed to combine the priorities of Care Coordination and Patient- and Caregiver-Centered Experience of Care into one domain for purposes of aligning the Hospital VBP Program domains with the CMS Quality Strategy. The domain name is often shortened to say PCCEC/CC. The HCAHPS measure, which includes the care transitions measure (CTM–3), currently comprises the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain.

This domain name has proven to be long and unwieldy. Therefore, we are proposing to change the domain name from Patient- and Caregiver-Centered Experience of Care/Care Coordination to, more simply, Person and Community Engagement beginning with the FY 2019 program year. We believe that this domain name captures two goals of the CMS Quality Strategy, as shown in the table below:

Hospital VBP program domain	CMS Quality strategy goal
Safety	Make Care Safer by Reducing Harm Caused in the Delivery of Care.

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[24] Mathematica Policy Research (November 2011). Reporting period and reliability of AHRQ, CMS 30-day and HAC Quality Measures—Revised. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf.*

[25] National Quality Forum QPS Measure Description for "Patient Safety for Selected Indicators (modified version of PSI90) (Composite Measure)" found at *https://www.qualityforum.org/QPS/MeasureDetails.aspx?standardID=321&print=0&entityTypeID=3.*

[26] First, section 1886(o)(2)(A) of the Act requires the Program to select measures that have been specified for the Hospital IQR Program. Second, section 1886(o)(2)(C)(i) of the Act requires the Hospital VBP Program to refrain from beginning the performance period for a new measure until data on the measure have been posted on *Hospital Compare* for at least one year. Finally, section 1886(o)(3)(C) of the Act requires that the Hospital VBP Program establish performance standards for each measure not later than 60 days prior to the beginning of the performance period.

Hospital VBP program domain	CMS Quality strategy goal
Efficiency and Cost Reduction	Make Care Affordable.
Clinical Care	Promote Effective Prevention and Treatment of Chronic Disease.
Person and Community Engagement	Promote Effective Communication and Coordination of Care.
	Strengthen Persons and Their Families as Partners in Their Care.
N/A	Work with Communities to Promote Best Practices of Healthy Living.

We are inviting public comments on this proposal.

c. Proposed Inclusion of Selected Ward Non-Intensive Care Unit (ICU) Locations in Certain NHSN Measures Beginning With the FY 2019 Program Year

The Hospital VBP Program has used the CLABSI measure since the FY 2015 program year and has used the CAUTI measure since the FY 2016 program year. Both measures use adult, pediatric, and neonatal intensive care unit (ICU) data to calculate performance standards and measure scores (79 FR 50061). In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50787), we expanded the CAUTI and CLABSI measures to selected ward (non-ICU) settings for the Hospital IQR Program, effective January 1, 2015 (78 FR 50787). Data were first posted on *Hospital Compare* in December 2015. Selected ward (non-ICU) locations are defined as adult or pediatric medical, surgical, and medical/surgical wards (78 FR 50787; 79 FR 50061). More information on the CLABSI and CAUTI measures can be found at: *http://www.cdc.gov/nhsn/pdfs/pscmanual/4psc_clabscurrent.pdf* and *http://www.cdc.gov/nhsn/pdfs/pscmanual/7psccauticurrent.pdf*, respectively.

In the FY 2015 and FY 2016 IPPS/LTCH PPS final rules, we discussed our intent to consider using data from selected ward (non-ICU) locations for the Hospital VBP Program beginning in the FY 2019 program year for purposes of calculating performance standards for the CAUTI and CLABSI measures (79 FR 50061; 80 FR 49556). Several public commenters supported our proposal to include performance data from non-ICU locations in the CLABSI and CAUTI measures beginning in the FY 2019 program year, noting that CLABSI and CAUTI measures are important targets for dedicated surveillance and prevention efforts outside the ICU setting (80 FR 49566).

Based on the public comments we have received in prior rulemaking, we are proposing to include the selected ward (non-ICU) locations in the CAUTI and CLABSI measures for the Hospital VBP Program beginning with the FY 2019 program year, with a baseline period of January 1, 2015 through December 31, 2015 and a performance period of January 1, 2017 through December 31, 2017. This expansion of the CAUTI and CLABSI measures aligns with the Hospital IQR Program. It also aligns with the HAC Reduction Program, which adopted the expansion of the CAUTI and CLABSI measures beginning with its FY 2018 program year (80 FR 49576 through 49578). This expansion is also consistent with the NQF reendorsement update to these measures, which allows application of the measures beyond ICU locations (78 FR 50787). The MAP conditionally supported the expansion of the CAUTI (MUC–S0138) and CLABSI (MUC–S0139) measures for the Hospital VBP Program on the condition of gaining experience publicly reporting these measure data, as detailed in the "Spreadsheet of MAP 2015 Final Recommendations."[27] We continue to believe this expansion of the measures would allow all hospitals, including hospitals that do not have ICU locations, to use the tools and resources of the NHSN for quality improvement and public reporting efforts.

We are inviting public comments on this proposal.

d. Summary of Previously Adopted Measures and Newly Proposed Measure Refinements for the FY 2019 Program Year

In summary, for the FY 2019 program year, we have finalized the following measure set and are proposing the refinement of certain NHSN measures, as indicated:

PREVIOUSLY ADOPTED MEASURES AND NEWLY PROPOSED MEASURE REFINEMENTS FOR THE FY 2019 PROGRAM YEAR ±

Short name	Domain/Measure name	NQF #
	Person and Community Engagement Domain *	
HCAHPS	HCAHPS + 3-Item Care Transition Measure	0166 0228
	Clinical Care Domain	
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0230
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization.	0229
MORT–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.	0468
THA/TKA	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550
	Safety Domain	
CAUTI **	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138

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[27] "Spreadsheet of MAP 2015 Final Recommendations" available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711* and "Process and Approach for MAP Pre-Rulemaking Deliberations 2015" available at: *http://www.qualityforum.org/Publications/2015/01/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations_2015.aspx.*

PREVIOUSLY ADOPTED MEASURES AND NEWLY PROPOSED MEASURE REFINEMENTS FOR THE FY 2019 PROGRAM YEAR[±]—Continued

Short name	Domain/Measure name	NQF #
CLABSI[**]	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI.	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	1716
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	1717
PSI 90	Patient Safety for Selected Indicators (Composite Measure)	0531
PC–01	Elective Delivery	0469
	Efficiency and Cost Reduction Domain	
MSPB	Payment-Standardized Medicare Spending Per Beneficiary (MSBP)	2158

[±] We are changing some of the short names for measures from previous years' rulemakings to align these names with the usage in the Hospital IQR Program, and we are changing some measure names from previous years' rulemakings to use complete NQF-endorsed measure names.

[*] We are proposing, in section IV.H.3.b. of the preamble of this proposed rule, to change the name of this domain from Patient- and Caregiver-Centered Experience of Care/Care Coordination domain to Person and Community Engagement domain beginning with the FY 2019 program year.

[**] Proposed to include selected ward (non-ICU) locations in the measure as discussed in section IV.H.3.c. of the preamble of this proposed rule.

4. Newly Proposed Measures and Measure Refinements for the FY 2021 Program Year and Subsequent Years

We consider measures for adoption based on the statutory requirements, including specification under the Hospital IQR Program, posting dates on the *Hospital Compare* Web site, and our priorities for quality improvement as outlined in the current CMS Quality Strategy, available at: ***https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html.***

Due to the time necessary to adopt measures, we often adopt policies for the Hospital VBP Program well in advance of the program year for which they will be applicable (for example, 76 FR 26490 through 26547; 76 FR 51653 through 51660; 76 FR 74527 through 74547; 77 FR 53567 through 53614; 78 FR 50676 through 50707; 78 FR 75120 through 75121; 79 FR 50048 through 50087; 80 FR 49556 through 49559).

a. Condition-Specific Hospital Level, Risk-Standardized Payment Measures

Providing high-value care is an essential part of our mission to provide better health care for individuals, better health for populations, and lower healthcare costs. Our aim is to encourage higher value care where there is the most opportunity for improvement, the greatest number of patients to benefit from improvements, and the largest sample size to ensure reliability. In order to incentivize innovation that promotes high-quality care at high value, we believe it is critical to examine measures of resource use, efficiency, and cost reduction.

In prior rules we have discussed our interest in expanding the Hospital VBP Program's Efficiency and Cost Reduction domain to include condition-specific or treatment-specific Medicare payment measures, and we have sought public comments (78 FR 50688; 79 FR 50066). In response to comments, we have stated that risk-adjusted standardized Medicare payments, viewed in light of other quality measures in a program, are an appropriate indicator of efficiency because they allow us to compare hospitals without regard to factors such as geography and teaching status. This comparison is particularly important with clinically coherent episodes because it distinguishes the degree to which practice pattern variation influences the cost of care. In addition, we have stated that the granularity of condition-specific or treatment-specific payment measures may provide specific actionable feedback to hospitals to implement targeted improvements. The observed differences in episode payments revealed by these measures may also encourage hospitals to assess local, postacute health care services (for example, SNF and home health services) to ensure that efficient services are available to all patients. Given these factors, we believe that the addition of condition-specific or treatment-specific payment measures to the Hospital VBP Program is necessary not only to facilitate a better understanding of service utilization and costs associated with conditions or treatments, but also as an important next step in the evolution of value-based purchasing to transform how Medicare pays for care and services.

We recognize that high or low payments to hospitals are difficult to interpret in isolation. Some high payment hospitals may produce better clinical outcomes when compared with low payment hospitals, while other high payment hospitals may not produce better outcomes. For this reason, payment measure results viewed in isolation are not necessarily an indication of quality. However, by viewing such information along with quality measure results, we believe that consumers, payers, and providers would be able to better assess the value of care. We believe that adopting condition-specific or treatment-specific payment measures for the Hospital VBP Program that can be more directly paired with clinical outcome measures, aligned by comparable populations, performance periods, or risk-adjustment methodologies, help move toward achievement of this goal. We also believe that adopting condition-specific or treatment-specific payment measures would create stronger incentives for appropriately reducing practice pattern variation to achieve the aim of lowering the cost of care and creating better coordinated care for Medicare beneficiaries.

In the Hospital VBP Program, we adopted the Medicare Spending per Beneficiary (MSPB) measure beginning with the FY 2015 program year to incentivize hospitals to redesign care systems in order to provide coordinated, high-quality, and cost-efficient care (77 FR 53590). Currently, the Hospital VBP Program measures efficiency by weighting and combining the MSPB measure with other quality measures in order to calculate each hospital's TPS. However, we have previously expressed our interest in expanding the Efficiency and Cost Reduction domain and continue to believe that additional supplemental measures would create incentives for greater coordination between hospitals and physicians to optimize the care they provide to Medicare beneficiaries (78 FR 50688; 79 FR 50066).

We believe that when examining variation in payments, an episode-of-care triggered by admission is meaningful for several reasons. First, hospitalizations represent brief periods of illness that require ongoing management post-discharge, and decisions made at the admitting hospital affect payments for care in the immediate postdischarge period. Second, attributing payments for a continuous episode-of-care to admitting hospitals may reveal variations in care decision-making and resource utilization. Third, an episode-of-care with a specified time period (30 days in the case of the measures proposed below) provides a standard observation period by which to compare all hospitals. For all of the reasons described above, we are proposing to add two condition-specific payment measures in the Hospital VBP Program that can be directly paired with existing clinical outcome measures in the program.

We are inviting public comments on the proposed measures as detailed below. We are further inviting public comment on the addition of other condition-specific or treatment-specific payment measures that are directly paired with quality measures, as well as episode-based payment measures not directly paired with quality measures, for future program years.

(1) Proposed New Measure for the FY 2021 Program Year: Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI) (NQF #2431)

Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for AMI (NQF #2431) (AMI Payment) is an NQF-endorsed measure assessing hospital risk-standardized payment associated with a 30-day episode-of-care for AMI. We adopted this measure in the Hospital IQR Program in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50802 through 50805). The measure includes Medicare FFS patients aged 65 or older admitted for an AMI and calculates payments for these patients over a 30-day episode-of-care, beginning with the index admission, using administrative claims data. In general, the measure uses the same approach to risk-adjustment as our 30-day outcome measures previously adopted for the Hospital VBP Program, including the AMI mortality measure. Initial measure data were posted on *Hospital Compare* in December 2014 and the full measure specifications are available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

AMI remains a high-volume condition that is one of the top 20 conditions contributing to Medicare costs.[28] There is evidence of variation in payment for AMI patients among hospitals; median 30-day risk-standardized payment (in 2013 dollars) for AMI was $21,620 and ranged from $12,862 to $29,802 for the July 2011 through June 2014 reporting period in the Hospital IQR Program.[29] This variation in payment suggests there is opportunity for improvement.

We believe it is important to adopt the AMI Payment measure because variation in payment may reflect differences in care decision-making and resource utilization (for example, treatment, supplies, or services) for patients with AMI both during hospitalization and immediately post-discharge. The AMI Payment measure also addresses the NQS priority and CMS Quality Strategy goal to make quality care more affordable. Lastly, the AMI Payment measure is intended to be paired with our 30-day AMI mortality measure, MORT–30–AMI, thereby directly linking payment to quality by the alignment of comparable populations and risk-adjustment methodologies to facilitate the assessment of efficiency and value of care.

We are proposing the AMI Payment measure beginning with the FY 2021 program year. The AMI Payment measure would be added to the Efficiency and Cost Reduction domain. The proposed measure fulfills all statutory requirements for the Hospital VBP Program based on our adoption of the measure in the Hospital IQR Program, and our posting of measure data on *Hospital Compare* for at least one year before the beginning of the performance period. The AMI Payment measure (MUC15–369) was reviewed by the MAP in December 2015 and did not receive support for adoption into the Hospital VBP Program.[30] The result of the MAP vote was 27 percent support, 15 percent conditional support, and 58 percent do not support. MAP members expressed concern that treatment-specific or condition-specific payment measures may overlap and double count services that are already captured in the MSPB measure. In addition, stakeholders expressed a desire to have more experience with the measure in the Hospital IQR Program to understand whether there may be unintended consequences or a need to adjust for sociodemographic status (SDS).

With respect to MAP stakeholder concerns that treatment-specific or condition-specific payment measures may overlap and double count services, we note that these measures cover topics of critical importance to quality improvement in the inpatient hospital setting. As discussed above, we selected these measures because we believe that it is appropriate to provide stronger incentives for hospitals to provide high-value and efficient care. We believe that even if some services were double counted, hospitals that offer quality service and maintain better results on the MSPB and condition-specific payment measures relative to other hospitals in the Hospital VBP Program could receive an increased benefit by performing well on both quality measures and payment measures. Furthermore, because hospitals would have bigger financial incentives, they would strive to perform better, which would lead to better quality. At the same time, however, we are proposing that the Efficiency and Cost Reduction domain remain weighted at 25 percent of the TPS even as additional payment measures may be adopted for this domain in the FY 2021 program year; therefore, the impact of poor performance on the MSPB measure or on any other particular payment measure would be reduced.

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[28] Torio, C.M. and Andrews, R.M., 2013. National inpatient hospital costs: The most expensive conditions by payer, 2011. In Agency for Healthcare Research and Quality, Healthcare Cost and Utilization Project Statistical Brief# 160. Available at: *https://www.hcup-us.ahrq.gov/reports/statbriefs/sb160.pdf.*

[29] 2015 Condition-Specific Measure Updates and Specifications Report Hospital-Level 30-Day Risk Standardized Payment Measures. AMI, HF, PN Payment Updates (zip file). Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[30] "Spreadsheet of MAP 2015–2016 Final Recommendations" available at: *http://www.qualityforum.org/map/* and "Process and Approach for MAP Pre-Rulemaking Deliberations 2016" found at: *http://www.qualityforum.org/Publications/2016/02/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations.aspx.*

In regard to MAP stakeholder concerns regarding the need to adjust for SDS, we note that the AMI Payment measure already incorporates a risk-adjustment methodology that accounts for age and comorbidities. We understand the important role that sociodemographic status plays in the care of patients. However, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on hospitals' results on our measures.

NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk-adjustment model.

Furthermore, ASPE is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

Finally, we note that some MAP members did express support for the AMI Payment measure and other condition-specific payment measures. Members agreed that the increased granularity provided by condition-specific payment measures will provide valuable feedback to hospitals for targeted improvement. A recent NQF-commissioned white paper also supports the position that cost or payment measures should be interpreted in the context of quality measures and that measures that link cost and quality are the preferred method of assessing hospital efficiency.[31] We believe that the condition-specific payment measures we are proposing, which directly pair with clinical outcome measures already in the Hospital VBP Program, follow this recommended approach. Based on our analysis of the issues surrounding condition-specific payment measures, we believe that the benefits of adopting this measure into the Hospital VBP Program outweigh any potential risks; however, we remain committed to monitoring for unintended consequences.

We are inviting public comments on this proposal.

(2) Proposed New Measure for the FY 2021 Program Year: Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Heart Failure (HF) (NQF #2436)

Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for HF (NQF #2436) (HF Payment) is an NQF-endorsed measure assessing hospital risk-standardized Medicare payment associated with a 30-day episode-of-care for heart failure. The measure includes Medicare FFS patients aged 65 or older admitted for heart failure and calculates payments for these patients over a 30-day episode-of-care, beginning with the index admission, using administrative claims data. In general, the measure uses the same approach to risk-adjustment as our 30-day outcome measures previously adopted for the Hospital VBP Program, including the HF mortality measure. We adopted this measure in the Hospital IQR Program in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50231 through 50235). Initial measure data were posted on *Hospital Compare* in July 2015 and the full measure specifications are available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

Heart failure is one of the leading causes of hospitalization for Americans 65 and over and costs roughly $34 billion annually.[32] [33] There is evidence of variation in Medicare payments at hospitals for heart failure patients; median 30-day risk-standardized payment (in 2013 dollars) among Medicare FFS patients aged 65 or older was $15,139, and ranged from $11,086 to $21,867 for the July 2011 through June 2014 reporting period in the Hospital IQR Program.[34] This variation in payment suggests there is opportunity for improvement.

We believe it is important to adopt the HF Payment measure because variation in payment may reflect differences in care decision making and resource utilization (for example, treatment, supplies, or services) for patients with heart failure both during hospitalization and immediately post-discharge. The HF Payment measure also addresses the NQS priority and CMS Quality Strategy goal to make quality care more affordable. Lastly, the HF Payment measure is intended to be paired with our 30-day HF mortality measure, MORT–30–HF, thereby directly linking payment to quality by the alignment of comparable populations and risk-adjustment methodologies to facilitate the assessment of efficiency and value of care.

We are proposing the HF Payment measure beginning with the FY 2021 program year. The HF Payment measure would be added to the Efficiency and Cost Reduction domain. The measure fulfills all statutory requirements for the Hospital VBP Program based on our adoption of the measure in the Hospital IQR Program and our posting of measure data on *Hospital Compare* for at least one year before the beginning of the performance period for this measure. The HF Payment measure (MUC15–322) was reviewed by the MAP in December 2015 and did not receive support for adoption into the Hospital VBP Program, due to the same concerns that we noted in our discussion of the AMI Payment measure.[35] The result of the MAP vote was 27 percent support, 8 percent conditional support, and 65 percent do not support. Although the final MAP decision was "do not support," we continue to believe that the NQF-endorsed HF Payment measure provides beneficiaries and hospitals with valuable information about relative value for an episode-of-care. We support the HF Payment measure for the same reasons that we noted in our general discussion of condition-specific payment measures in section IV.H.4.a. of the preamble of this proposed rule and in our discussion of the AMI Payment measure in section IV.H.4.a.(2) of the preamble of this proposed rule.

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[31] Ryan A.M., Tompkins C.P. Efficiency and Value in Healthcare: Linking Cost and Quality Measures. Washington, DC: NQF; 2014.

[32] Russo C.A., Elixhauser, A. Hospitalizations in the Elderly Population, 2003. Agency for Healthcare Research and Quality. 2006.

[33] Heidenriech P.A., Trogdon J.G., Khavjou O.A., Butler J, Dracup K., Ezekowitz M.D., et al. Forecasting the future of cardiovascular disease in the United States: A policy statement from the American Heart Association. Circulation. 2011;123(8):933–44.

[34] 2015 Condition-Specific Measure Updates and Specifications Report Hospital-Level 30-Day Risk-Standardized Payment Measures. AMI, HF, PN Payment Updates (zip file). Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[35] "Spreadsheet of MAP 2015–2016 Final Recommendations" available at: *http://www.qualityforum.org/map/* and "Process and Approach for MAP Pre-Rulemaking Deliberations 2016" found at: *http://www.qualityforum.org/Publications/2016/02/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations.aspx.*

We note that some MAP members did express support for the HF Payment measure and other condition-specific payment measures. Members agreed that the increased granularity provided by condition-specific payment measures will provide valuable feedback to hospitals for targeted improvement. In addition, we believe that the condition-specific payment measures we are proposing, which directly pair with clinical outcome measures already in the Hospital VBP Program, follow the recommended approach outlined in the NQF white paper on how best to measure efficiency.[36] Based on our analysis of the issues surrounding condition-specific payment measures, we believe that the benefits of adopting this measure into the Hospital VBP program outweigh any potential risks. However, we remain committed to monitoring for unintended consequences.

We are inviting public comments on this proposal.

(3) Proposed Scoring Methodology for the Proposed AMI Payment and HF Payment Measures

We are proposing to score the proposed AMI Payment and HF Payment measures using the same methodology we use to score the MSPB measure, so that all measures in the Efficiency and Cost Reduction domain are scored in the same manner and have the same case minimum threshold.

For achievement points, we are proposing to calculate a spending ratio of AMI spending and HF spending for each hospital to the median AMI spending and median HF spending, respectively, across all hospitals during the performance period. We would then use each hospital's AMI spending ratio and HF spending ratio to calculate between 0 and 10 achievement points. We are proposing to set the achievement thresholds at the median AMI spending ratio and HF spending ratio across all hospitals during the performance period. We are proposing to set the benchmarks at the mean of the lowest decile of the AMI spending ratios and the HF spending ratios during the performance period. Therefore, a hospital whose individual AMI spending or HF spending ratios fall above the achievement threshold would score 0 achievement points on the measure. A hospital for which individual AMI spending or HF spending ratios fall at or below the benchmark would score the maximum 10 achievement points on the measure. A hospital for which individual AMI spending or HF spending ratios fall at or below the achievement threshold but above the benchmark would score between 1 and 9 points according to the following formula:

[9 * ((achievement threshold − Hospital's performance period ratio)/(achievement threshold − benchmark))] + 0.5

For improvement points, we are proposing to calculate a spending ratio of AMI spending and HF spending for each hospital to the median AMI spending and median HF spending, respectively, across all hospitals during the performance period. We would then use each hospital's AMI spending ratio and the HF spending ratio to calculate between 0 and 9 improvement points by comparing each hospital's ratio to its own performance during the baseline period. We are proposing to set the improvement benchmark as the mean of the lowest decile of AMI spending and HF spending ratios across all hospitals. Therefore, a hospital for which AMI spending or HF spending ratios are equal to or higher than its baseline period ratios would score 0 improvement points on the measure. If a hospital's score on the measure during the performance period is less than its baseline period score but above the benchmark, the hospital would receive a score of 0 to 9 according to the following formula:

[10 * ((Hospital baseline period ratio − Hospital performance period ratio)/(Hospital baseline period ratio − benchmark))] − 0.5

For more information about the proposed scoring methodology for the AMI Payment and HF Payment measures, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51654 through 51656) and to 42 CFR 412.160 where we discuss the MSPB measure's identical scoring methodology in detail.

In order to codify this scoring methodology for the proposed payment measures, we are proposing to amend our regulations at 42 CFR 412.160 to revise the definitions of "Achievement threshold" and "Benchmark" to reflect this methodology, not just for the MSPB measure, but more generally for all measures in the Efficiency and Cost Reduction domain.

We also considered and seek public feedback on scoring the AMI Payment and HF Payment measures using the same methodology that we use to score most other measures, including the MORT–30–AMI and MORT–30–HF measures. Under that scoring methodology, hospitals receive achievement points along an achievement range, which is a scale between the achievement threshold (the minimum level of hospital performance required to receive achievement points) and the benchmark (the mean of the top decile of hospital performance during the baseline period). A hospital receives improvement points for a measure if the hospital improves upon its measure score from its own baseline period measure score (76 FR 26514). We decided to propose the scoring methodology that more closely aligns with the MSPB measure because we believe it would be helpful for hospitals to be compared against performance standards constructed from more current performance period data, given potential changes in Medicare payment policy, changes in market forces, and changes in utilization practices.

We are inviting public comment on the proposed scoring methodology in the calculation of achievement and improvement points for the AMI Payment and HF Payment measures beginning with the FY 2021 program year.

In addition, we are considering adopting a scoring methodology for a future program year that would assess quality measures and efficiency measures in tandem to produce a composite score reflective of value. To support the goals of value-based purchasing and to provide consumers and purchasers with information about value of care provided by hospitals, we are soliciting public comments on ways we can incorporate scoring value into the Hospital VBP Program. The concept of value reflects highest quality achieved with most efficiency or least costs. Currently, the Hospital VBP Program assesses quality and efficiency separately through distinct performance measures and domains. Because each domain is weighted and combined to determine each hospital's TPS, a hospital could earn a higher payment adjustment relative to other hospitals by performing well on the quality-related domains but without performing well in the Efficiency and Cost Reduction domain, or vice versa. Without a measure or score for value that reflects both quality and costs, our ability to assess value is limited.

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[36] Ryan A.M., Tompkins C.P. Efficiency and Value in Healthcare: Linking Cost and Quality Measures. Washington, DC: NQF; 2014.

There are various different ways value could be incorporated into the Hospital VBP Program. We are seeking public comments on two general approaches. First, specific measures of value could be developed by measure developers and incorporated into the Hospital IQR Program and then the Hospital VBP Program through the measure development process. This may be a lengthy process and will depend upon interest from measure developers. However, specific measures of value could be more interpretable by consumers, and would have rates that could be trended, benchmarked, and scored using the current Hospital VBP Program scoring methodology for assessing achievement and improvement.

A second potential approach is for the Hospital VBP Program to use the Program's scoring methodology to incorporate value based on the performance of hospitals by either: (a) Comparing scores on specific quality and cost measures; or (b) comparing quality and efficiency domain scores. First, the measure-specific approach could target high-cost, high clinical-impact conditions by pairing condition-specific quality and cost measures, such as by assessing a ratio of a hospital's reported quality over costs. A value score based on the paired clinical outcome and cost measures could be incorporated into the existing Efficiency and Cost Reduction domain (or Clinical Care or Safety domains) or included in a separate new 'Value' domain. Alternatively, a domain-based value scoring approach could be similar to the current quality/cost tiering approach in the Physician Value-Based Modifier Program, which tiers providers into nine high, average, or low cost and quality (or "value") categories to determine payments. The domain-based value score could be weighted and incorporated into the calculation of a hospital's overall Hospital VBP Program TPS along with the other existing domains, or potentially as a multiplier or adjuster to additionally reward higher value hospitals.

We welcome the public's feedback and suggestions on how to appropriately incorporate the concept of value in the Hospital VBP Program, and we are inviting specific suggestions on how to measure or score value that will be meaningful to consumers, purchasers, and providers.

b. Proposed Update to an Existing Measure for the FY 2021 Program Year: Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization (NQF #0468) (Updated Cohort)

The Hospital 30-Day, All-Cause, RSMR Following Pneumonia Hospitalization (NQF #0468) (MORT–30–PN (updated cohort)) measure is a risk-adjusted, NQF-endorsed mortality measure monitoring mortality rates following PN hospitalizations. As part of the CMS measure reevaluation process, the MORT–30–PN measure underwent a substantive revision, which expanded the measure cohort to include: (1) Patients with a principal discharge diagnosis of pneumonia (the current reported cohort); (2) patients with a principal discharge diagnosis of aspiration pneumonia; and (3) patients with a principal discharge diagnosis of sepsis (excluding severe sepsis) with a secondary diagnosis of pneumonia coded as present on admission. For the purposes of describing the refinement of this measure, we note that "cohort" is defined as the hospitalizations, or "index admissions," that are included in the measure and evaluated to ascertain whether the patient subsequently died within 30 days of the index admission. This cohort is the set of hospitalizations that meet all of the inclusion and exclusion criteria.

The Hospital IQR Program adopted this measure refinement of MORT–30–PN (updated cohort) in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49653 through 49660), with initial MORT–30–PN (updated cohort) data to be posted on *Hospital Compare* on or around July 21, 2016. The MORT–30–PN (updated cohort) measure (MUC–E0468) was included on the "List of Measures Under Consideration for December 1, 2014" and received conditional support from the MAP, pending NQF endorsement of the updated cohort as detailed in the "Spreadsheet of MAP 2015 Final Recommendations."[37] The full measure specifications are available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

This refinement to the MORT–30–PN measure was adopted to more accurately reflect quality and outcomes for patients with pneumonia. Recent evidence has shown an increase in the use of sepsis as a principal diagnosis code among patients hospitalized with pneumonia.[38] In response to this emerging evidence, we examined coding patterns across hospitals caring for Medicare patients and sought to forecast the impact of enhancing or broadening the measure cohort to include the complete patient population, at each hospital, who are receiving clinical management and treatment for pneumonia. Our findings were consistent with a published study.[39] That is, our results suggested that there is: (1) An increasing use of sepsis as a principal discharge diagnoses for pneumonia patients; and (2) wide variation across hospitals in the use of these codes. These published studies and CMS analyses also show that hospitals that use sepsis codes for the principal diagnosis frequently have better performance on the currently adopted MORT–30–PN measure. This coding practice improves performance on the measure because patients with greatest severity of illness (for example, those with sepsis) are systematically excluded from the measure under current measure specifications, leaving only patients with less severity of illness in the cohort.

In addition to assessing the use of the principal diagnosis codes of sepsis, we also analyzed coding patterns and the impact of expanding the pneumonia measure to include patients with the principal diagnosis of aspiration pneumonia. We noted after our analyses that aspiration pneumonia: (1) Is a common reason for pneumonia hospitalization, particularly among the elderly; (2) is currently not included in the CMS hospital outcome measure specifications for pneumonia patients; and (3) appears to be similarly subject to variation in diagnosis, documentation, and coding. The findings of published studies and CMS analyses suggested that a MORT–30–PN measure with an enhanced or broader cohort would ensure that the population of patients with pneumonia is more complete and comparable across hospitals.

We are proposing this measure refinement for the Hospital VBP

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[37] "Spreadsheet of MAP 2015 Final Recommendations" available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711* and "Process and Approach for MAP Pre-Rulemaking Deliberations 2015" available at: *http://www.qualityforum.org/Publications/2015/01/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations_2015.aspx.*

[38] Lindenauer P.K., Lagu T., Shieh M.S., Pekow P.S., Rothberg M.B. Association of diagnostic coding with trends in hospitalizations and mortality of patients with pneumonia, 2003–2009. Journal of the American Medical Association. Apr 4 2012;307(13):1405–1413.

[39] Rothberg M.B., Pekow P.S., Priya A., Lindenauer P.K. Variation in diagnostic coding of patients with pneumonia and its association with hospital risk-standardized mortality rates: A cross-sectional analysis. Annals of Internal Medicine. Mar 18 2014;160(6):380–388.

Program based on our adoption of the measure refinement in the Hospital IQR Program, and our posting of measure data on *Hospital Compare* for at least 1 year prior to the start of the measure performance period. In addition, the MORT–30–PN (updated cohort) measure addresses a high volume, high cost condition. The measure aligns with the NQS priority and CMS Quality Strategy Goal of "Effective Prevention and Treatment of Chronic Disease." Based on the continued high risk of mortality after pneumonia hospitalizations, we are proposing to add it to the Clinical Care domain beginning with the FY 2021 program year.

We are inviting public comments on this proposal.

5. Proposed New Measure for the FY 2022 Program Year: Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2558)

The Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following CABG Surgery (NQF #2558) (MORT–30–CABG) measure is a risk-adjusted, NQF-endorsed mortality measure monitoring mortality rates following CABG hospitalizations. This measure includes Medicare FFS patients aged 65 or older who receive a qualifying CABG procedure and assesses hospitals' 30-day, all-cause risk-standardized rate of mortality, beginning with the date of the index procedure. The measure is calculated using administrative claims data. In general, the measure uses the same approach to risk adjustment as our 30-day outcome measures previously adopted for the Hospital VBP Program. We adopted this measure in the Hospital IQR Program in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50224 through 50227). Initial measure data were posted on *Hospital Compare* in July 2015 and the full measure specifications are available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

CABG is a priority area because it is a common procedure associated with considerable morbidity, mortality, and healthcare spending. In the United States, over 200,000 CABG procedures are performed annually, and the majority of procedures are performed on Medicare beneficiaries.[40] In 2012, Medicare beneficiaries had 121,744 CABG surgery admissions, with or without percutaneous coronary intervention or valve surgery.[41] CABG surgeries are costly procedures that account for a large percentage of cardiac surgeries performed nationally. For example, isolated CABG surgeries accounted for almost half (40.02 percent) of all cardiac surgery hospital admissions in Massachusetts in FY 2012.[42] This provides an example of the frequency in which a CABG is performed for a patient admitted for cardiac surgery. The average Medicare payment was $32,564 for CABG without valve and $48,461 for CABG plus valve surgeries in 2011.[43]

Mortality rates following CABG surgery are not insignificant and vary across hospitals. For the July 2011 through June 2014 Hospital IQR Program reporting period, the median hospital-level risk-standardized mortality rate after CABG was 3.1 percent and ranged from 1.6 percent to 9.2 percent.[44] Variation in mortality rates following CABG surgery can be seen not only nationally, but also within a single State. Within the State of New York, the risk-adjusted mortality rate among patients who were discharged after CABG surgery (without any other major heart surgery earlier in the hospital stay) ranged from 0.0 percent to 4.58 percent in 2011.[45] Variation in risk-standardized mortality rates among U.S. hospitals suggests that there is room for improvement.

An all-cause, risk-adjusted mortality measure for patients who undergo CABG surgery would provide hospitals with an incentive to reduce mortality through improved coordination of perioperative care and discharge planning. This is further supported by the success of registry-based mortality measures in reducing CABG mortality rates. For example, CABG mortality in California declined from 2.9 percent in 2003, the first year that the State implemented a mandatory CABG mortality reporting measure, to 2.1 percent in 2012.[46]

We are proposing the MORT–30–CABG measure for the Hospital VBP Program beginning with the FY 2022 program year because it addresses a high-volume, high-cost procedure with variation in performance. The measure also aligns with the CMS Quality Strategy Goal of Effective Prevention and Treatment of Chronic Disease. The measure fulfills all statutory requirements for the Hospital VBP Program based on our adoption of the measure in the Hospital IQR Program and our posting of measure data on *Hospital Compare* for at least one year before the beginning of the measure performance period. The MAP supported the inclusion of the MORT–30–CABG measure (MUC15–395) in the Hospital VBP Program as detailed in the "Spreadsheet of MAP 2016 Final Recommendations."[47] Based on the continued high risk of mortality after CABG hospitalizations, we are proposing to add this measure to the Clinical Care domain beginning with the FY 2022 program year.

We are inviting public comments on this proposal.

6. Previously Adopted and Newly Proposed Baseline and Performance Periods

a. Background

Section 1886(o)(4) of the Act requires the Secretary to establish a performance period for the Hospital VBP Program that begins and ends prior to the beginning of such fiscal year. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49561 through 49562) for the baseline and performance periods for the Clinical Care, Person and Community Engagement, Safety, and

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[40] Fingar, K.R., Stocks, C., Weiss, A.J. and Steiner, C.A., 2014. Most frequent operating room procedures performed in U.S. hospitals, 2003–2012. In Agency for Healthcare Research and Quality, Healthcare Cost and Utilization Project Statistical Brief #186. Available at: *https://www.hcup-us.ahrq.gov/reports/statbriefs/sb186-Operating-Room-Procedures-United-States-2012.pdf.*

[41] Culler S.D., Kugelmass A.D., Brown P.P., Reynolds M.R., Simon A.W. Trends in coronary revascularization procedures among Medicare beneficiaries between 2008 and 2012. Circulation. 2014 Dec 22: CIRCULATIONAHA–114.

[42] Massachusetts Data Analysis Center. Adult Coronary Artery Bypass Graft Surgery in the Commonwealth of Massachusetts: Hospital and Surgeons Risk-Standardized 30-Day Mortality Rates. Fiscal Year 2012 Report. Available at: *http://www.massdac.org/wp-content/uploads/CABG-FY2012-Update.pdf.*

[43] Pennsylvania Health Care Cost Containment Council. Cardiac Surgery in Pennsylvania 2011–2013. Harrisburg; 2013:60.

[44] September 2015 Medicare Hospital Performance Report on Outcome Measures: Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/OutcomeMeasures.html.*

[45] New York State Department of Health. Adult Cardiac Surgery in New York State 2009–2011. Available at: *https://www.health.ny.gov/statistics/diseases/cardiovascular/heart_disease/docs/2009-2011_adult_cardiac_surgery.pdf.*

[46] California Office of Statewide Health Planning and Development. CABG Outcomes Reporting Program. The California Report on Coronary Artery Bypass Graft Surgery: 2003–2012 Trendlines. Available at: *http://www.oshpd.ca.gov/hid/Products/Clinical_Data/CABG/03-12_Trends.html or http://www.oshpd.ca.gov/HID/Products/Clinical_Data/CABG/2012/ExecutiveSummary.pdf.*

[47] "Spreadsheet of MAP 2015–2016 Final Recommendations" available at: *http://www.qualityforum.org/map/* and "Process and Approach for MAP Pre-Rulemaking Deliberations 2016" found at *http://www.qualityforum.org/Publications/2016/02/Process_and_Approach_for_MAP_Pre-Rulemaking_Deliberations.aspx.*

Efficiency and Cost Reduction domains that we have adopted for the FY 2018 program year. In past final rules, we have proposed and adopted a new baseline and performance period for each program year for each domain in each final rule. This year, we are proposing to adopt the following baseline and performance periods for all future program years, unless otherwise noted in future rulemaking.

b. Patient- and Caregiver-Centered Experience of Care/Care Coordination Domain (Proposed Person and Community Engagement Domain)

Since the FY 2015 program year, we have adopted a 12-month baseline period and a 12-month performance period for measures in the proposed Person and Community Engagement domain (currently referred to as the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain) (77 FR 53598; 78 FR 50692; 79 FR 50072; 80 FR 49561). We continue to believe that a 12-month period provides us sufficient data on which to score hospital performance.

Therefore, we are proposing to adopt this baseline and performance period length for the FY 2019 program year and all future program years, unless otherwise noted in future rulemaking. Therefore, for the FY 2019 program year and future program years, we are proposing to adopt a performance period that runs on the calendar year 2 years prior to the applicable program year. We are proposing to adopt a baseline period that runs on the calendar year 4 years prior to the applicable program year. Applying these proposed new policies, for the FY 2019 program year, the baseline period for the Person and Community Engagement domain (proposed name change) would run from January 1, 2015 through December 31, 2015. The performance period would run from January 1, 2017 through December 31, 2017.

c. Efficiency and Cost Reduction Domain

(1) MSPB Measure

Since the FY 2016 program year, we have adopted a 12-month baseline period and a 12-month performance period for the MSPB measure in the Efficiency and Cost Reduction domain (78 FR 50692; 79 FR 50072; 80 FR 49562). We continue to believe that a 12-month period for this measure provides sufficient data on which to score hospital performance. We are proposing to adopt this baseline and performance period length for the FY 2019 program year and all future program years, unless otherwise noted in future rulemaking. Therefore, for the FY 2019 program year and future program years, we are proposing to adopt a performance period that runs on the calendar year 2 years prior to the applicable program year. We are proposing to adopt a baseline period that runs on the calendar year 4 years prior to the applicable program year. Applying these proposed new policies, for the FY 2019 program year, the baseline period for the MSPB measure would run from January 1, 2015 through December 31, 2015. The performance period would run from January 1, 2017 through December 31, 2017.

(2) AMI Payment and HF Payment Measures in the FY 2021 Program Year

We are also proposing to adopt the AMI Payment and HF Payment measures as two new measures for the Efficiency and Cost Reduction domain beginning in the FY 2021 program year. In order to adopt the measures as early as feasible into the Hospital VBP Program, we are proposing to adopt a 36-month baseline period and a 24-month performance period. Therefore, for the FY 2021 program year, we are proposing to adopt a 24-month performance period that runs from July 1, 2017 to June 30, 2019. We are proposing to adopt a 36-month baseline period that runs from July 1, 2012 to June 30, 2015.

We believe that using a 24-month performance period for the AMI Payment and HF Payment measures, rather than a 36-month performance period, in the FY 2021 program year would accurately assess the quality of care provided by hospitals and would not substantially change hospitals' performance on the measure. To determine the viability of using a 24-month performance period to calculate the AMI Payment and HF Payment measures' scores, we compared the measure score reliability for a 24-month and 36-month performance period. We calculated the Intraclass Correlation Coefficient (ICC) to determine the extent to which assessments of a hospital using different but randomly selected subsets of patients produces similar measures of hospital performance.[48] We calculated the risk-standardized payment (RSP) using a random split-sample of a 36-month performance period (we used July 1, 2012 through June 30, 2015).

For both the 36-month and the 24-month performance periods, we obtained two RSPs for each hospital, using an entirely distinct set of patients from the same time period. If the RSPs for both the 36-month and the 24-month performance periods agree, we can demonstrate that the measure assesses the quality of the hospital rather than the types of patients treated. To calculate agreement between these measure subsets, we calculated the ICC (2,1)[49] for both the 36-month and 24-month performance periods.

For the AMI Payment measure, there were 459,874 index admissions and 2,342 hospitals that met the minimum threshold for reporting a measure result (at least 25 cases) in the 36-month performance period. We also calculated the RSP using a random split-sample of the combined 24-month performance period (we used July 1, 2012 through June 30, 2014). There were 309,067 index admissions and 2,141 hospitals that met the minimum threshold for reporting a measure result in the 24-month performance period.

For the 36-month performance period, the ICC for the two independent assessments of each hospital was 0.775. For the 24-month performance period, the ICC for the two independent assessments of each hospital was 0.742. Therefore, the data subsets showcase "substantial" agreement of hospital performance, and we can demonstrate that, even with a 24-month performance period, the measure assesses the quality of care provided at the hospital rather than the types of patients that these hospitals treat.[50]

To assess whether using 24 months of data instead of 36 months of data changes the performance in the same hospital, we compared the percent change in a hospital's predicted/expected (P/E) ratio. For hospitals that met the minimum case threshold in the 24-month performance period, the median percent change was −0.06 percent (with an interquartile range of −1.7 percent to 1.5 percent). These results suggest minimal difference in same-hospital performance when using a 24-month measurement period.

To determine the viability of using a 24-month performance period for the HF Payment measure, we assessed reliability and change in hospital performance for a 24-month and 36-month performance period using the same process as the AMI Payment measure. For the HF Payment measure, there were 877,856 index admissions and 2,981 hospitals that met the minimum threshold for reporting a measure result (at least 25 cases) in the 36-month performance period. We also calculated the RSP using a random split-sample of a 24-month performance period (we used July 1, 2012 through June 30, 2014). There were 580,741 index admissions and 2,883 hospitals that met the minimum threshold for reporting a measure result in the 24-month performance period.

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[48] Shrout P., Fleiss J. Intraclass Correlations: Uses in Assessing Rater Reliability. Pyschol Bull. Mar 1979;86(2):420–428.

[49] Shrout P., Fleiss J. Intraclass Correlations: Uses in Assessing Rater Reliability. *Pyschol Bull.* Mar 1979;86(2):420–428.

[50] Landis J, Koch G. The Measurement of Observer Agreement for Categorical Data. *Biometrics.* Mar 1997 1977;33(1):159–174.

For the 36-month performance period, the ICC for the two independent assessments of each hospital was 0.83. For the 24-month performance period, the ICC for the two independent assessments of each hospital was 0.81. Therefore, the data subsets showcase "almost perfect" agreement of hospital performance, and we can demonstrate that, even with a 24-month performance period, the measure assesses the quality of care provided at the hospital rather than the types of patients that these hospitals treat.[51]

To assess whether using a 24-month performance period instead of a 36-month performance period changes the performance in the same hospital, we compared the percent change in a hospital's P/E ratio. For hospitals that met the minimum case threshold in the 24-month performance period, the median percent change for hospitals' P/E ratio using 24-month performance periods compared with 36-month performance periods was −0.02 percent (with an interquartile range of −1.9 percent to 1.8 percent). These results suggest minimal difference in same-hospital performance when using a 24-month measurement period.

Therefore, we believe that using a 24-month performance period rather than a 36-month performance period would not substantially change hospitals' performance on the AMI Payment and HF Payment measures. In sum, based on the analyses described earlier, we believe that using 24-month performance periods, rather than 36-month performance periods, for the initial performance period for this measure would accurately assess the quality of care provided by that hospital and would not substantially change that hospital's performance on the measure.

(3) AMI Payment and HF Payment Measures in the FY 2022 Program Year

For the FY 2022 program year, we are proposing to adopt a 36-month performance period and a 36-month baseline period for the AMI Payment and HF Payment measures. We have stated in past rules that we would strive to adopt 36-month performance periods and baseline periods when possible to accommodate the time needed to process measure data and to ensure that we collect enough measure data for reliable performance scoring for all mortality measures (80 FR 49588; 79 FR 50057; 78 FR 50074). Therefore, for the FY 2022 program year, we are proposing to adopt a 36-month performance period that runs from July 1, 2017 to June 30, 2020. We are proposing to adopt a 36-month baseline period that runs from July 1, 2012 to June 30, 2015.

d. Safety Domain

Since the FY 2016 program year, we have adopted a 12-month baseline period and 12-month performance period for all measures in the Safety domain, with the exception of the PSI 90 measure (78 FR 50692; 79 FR 50071; 80 FR 49562). We continue to believe that a 12-month period for these measures provides us sufficient data on which to score hospital performance.

Therefore, we are proposing to adopt a 12-month baseline period and a 12-month performance period for all measures in the Safety domain, with the exception of the PSI 90 measure for the FY 2019 program year and all future program years, unless otherwise noted in future rulemaking. Under this proposed policy, for the FY 2019 program year and future program years, we are proposing to adopt a performance period that runs on the calendar year 2 years prior to the applicable program year. We are proposing to adopt a baseline period that runs on the calendar year 4 years prior to the applicable program year. Applying these proposed new policies, for the FY 2019 program year, the baseline period for all measures in the Safety domain except for the PSI 90 measure would run from January 1, 2015 through December 31, 2015. The performance period would run from January 1, 2017 through December 31, 2017.

As discussed in section IV.H.2.a. of the preamble of this proposed rule, we are proposing to shorten the performance period for the PSI 90 measure in the FY 2018 program year. Under this proposal, the performance period for the PSI 90 measure for the FY 2018 program year would be July 1, 2014 through September 30, 2015. As stated earlier, the baseline period for the measure for FY 2018 that we previously established would not change.

e. Clinical Care Domain

(1) Currently Adopted Measures in the Clinical Care Domain

For the FY 2019, FY 2020, and FY 2021 program years, we have adopted a 36-month baseline period and a 36-month performance period for currently adopted measures in the Clinical Care domain (78 FR 50692 through 50694; 79 FR 50073; 80 FR 49563).[52] For the FY 2022 program year, we are proposing to adopt a 36-month performance period and a 36-month baseline period for each of the other measures in the Clinical Care domain, the MORT–30–AMI, MORT–30–HF, and MORT–30–COPD measures, as well as the newly proposed MORT–30–CABG measure. The performance periods for these measures would run for 36-months from July 1, 2017 through June 30, 2020. The baseline period would run from July 1, 2012 through June 30, 2015. We are proposing that the THA/TKA measure performance period would run from April 1, 2017 through March 31, 2020. The baseline period would run from April 1, 2012 through March 31, 2015.

(2) MORT–30–PN (Updated Cohort) Measure in the FY 2021 Program Year

In order to adopt the newly proposed MORT–30–PN (updated cohort) measure into the Hospital VBP Program as early as feasible, we are proposing to adopt a 36-month baseline period and a 23-month performance period for the FY 2021 program year. We are proposing to adopt a 23-month performance period because the measure will not be posted on *Hospital Compare* for one year until July 21, 2017. We are proposing to begin the performance period on August 1, 2017 to accommodate this statutory requirement.

We believe that using a 23-month performance period for the MORT–30–PN (updated cohort) measure, rather than a 36-month performance period, in the FY 2021 program year would accurately assess the quality of care provided by hospitals and would not substantially change hospitals' performance on the measure. To determine the viability of using a 23-month performance period to calculate the MORT–30–PN (updated cohort) measure score, we compared the measure score reliability for a 23-month and a 36-month performance period. We calculated the ICC to determine the extent to which assessments of a hospital using different but randomly selected subsets of patients produces similar measures of hospital performance. We calculated the RSMR using a random split-sample of the combined 36-month performance period (we used July 1, 2012 through June 30, 2015). There were 1,292,701 index admissions and 3,103 hospitals that met the minimum threshold for reporting a measure result (at least 25 cases) in the 36-month performance period. We also calculated the RSMR using a random split-sample of the combined 23-month performance period (we used July 1, 2012 through May 31, 2014). There were 798,746 index admissions and 3,043 hospitals that met the minimum threshold for reporting a measure result in the 23-month performance period.

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[51] Landis J., Koch G. The Measurement of Observer Agreement for Categorical Data. *Biometrics.* Mar 1997 1977;33(1):159–174.

[52] The currently adopted measures in the Clinical Care domain include: MORT–30–AMI, MORT–30–HF, MORT–30–PN, and THA/TKA. The THA/TKA measure was added for the FY 2019 program year with a 36-month baseline period and a 24-month performance period (79 FR 50072), but we have since adopted 36-month baseline and performance periods for the FY 2021 program year (80 FR 49563). We intend to continue having 36-month baseline periods and 36-month performance periods in the future for all measures in the Clinical Care domain.

For both the 36-month data and the 23-month performance periods, we obtained two RSMRs for each hospital, using an entirely distinct set of patients from the same time period. If the RSMRs for both the 36-month subset and the 23-month performance periods agree, we can demonstrate that the measure assesses the quality of the hospital rather than the types of patients treated. To calculate agreement between these measure subsets, we calculated the ICC for both the 36-month and 23-month performance periods.

For the 36-month data performance period, the agreement between the two independent assessments of each hospital was 0.69. For the 23-month data performance period, the agreement between the two independent assessments of each hospital was 0.58. Therefore, the data subsets showcase "moderate" agreement of hospital performance, and we can demonstrate that, even with a 23-month performance period, the measure moderately assesses the quality of care provided at the hospital rather than the types of patients that these hospitals treat.[53]

To assess whether using a 23-month performance period instead of a 36-month performance period changes the performance in the same hospital, we compared the percent change in a hospital's RSMR. In some cases, changing the performance period from 36 months to 23 months resulted in hospitals failing to meet the case threshold to report a measure score; therefore, these hospitals were removed from the measure. For the remaining hospitals, the median percent change was 1.52 percent (with an interquartile range of 2.32 percent to 5.32 percent). These results suggest minimal difference in hospital performance when using a 23-month measurement period.

Therefore, we believe that using 23 months of data rather than 36 months of data would not substantially change hospitals' performance on this measure. In summary, based on the analyses further described earlier, we believe that using 23 months of data, rather than 36 months of data, for the initial performance period for this measure would, with moderate accuracy, assess the quality of care provided by that hospital. In addition, it would not substantially change that hospital's performance on the measure.

Further, adopting this proposed performance period would enable us to include the updated measure cohort in the FY 2021 Hospital VBP Program, which would ensure that MORT–30–PN more accurately reflects quality and outcomes for patients with pneumonia. Therefore, for the MORT–30–PN (updated cohort) measure, we are proposing a performance period that would run from August 1, 2017 through June 30, 2019 for the FY 2021 program year. The baseline period would run from July 1, 2012 through June 30, 2015.

(3) MORT–30–PN (Updated Cohort) Measure in the FY 2022 Program Year

For the FY 2022 program year and subsequent years, we are proposing to lengthen the MORT–30–PN (updated cohort) performance period to nearly a 36-month performance period (35 months) and continue to adopt a 36-month baseline period. For the FY 2022 program year, we are proposing a performance period that would run from August 1, 2017 through June 30, 2020. The baseline period would run from July 1, 2012 through June 30, 2015.

f. Summary of Previously Adopted and Newly Proposed Baseline and Performance Periods for the FY 2018, FY 2019, FY 2020, FY 2021, and FY 2022 Program Years

The tables below summarize the baseline and performance periods that we are proposing to adopt (and include previously adopted baseline and performance periods for the Clinical Care domain).

NEWLY PROPOSED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2018 PROGRAM YEAR

Domain	Baseline period	Performance period
Safety:		
• PSI 90*	July 1, 2010–June 30, 2012	July 1, 2014–September 30, 2015.

*We are proposing to shorten the performance period for the PSI 90 measure for the FY 2018 program year as discussed in section IV.H.2.a. of the preamble of this proposed rule.

PREVIOUSLY ADOPTED AND NEWLY PROPOSED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2019 PROGRAM YEAR

Domain	Baseline period	Performance period
Person and Community Engagement:		
• HCAHPS + 3-Item Care Transition	January 1, 2015–December 31, 2015.	January 1, 2017–December 31, 2017.
Clinical Care:		
• Mortality (MORT–30–AMI, MORT–30–HF, MORT–30–PN)*	• July 1, 2009–June 30, 2012	• July 1, 2014–June 30, 2017.
• THA/TKA*	• July 1, 2010–June 30, 2013	• January 1, 2015–June 30, 2017.
Safety:		

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[53] Landis J, Koch G. The Measurement of Observer Agreement for Categorical Data. *Biometrics.* Mar 1997 1977;33(1):159–174.

PREVIOUSLY ADOPTED AND NEWLY PROPOSED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2019 PROGRAM YEAR—Continued

Domain	Baseline period	Performance period
• PSI 90	• July 1, 2011–June 30, 2013	• July 1, 2015 through June 30, 2017.
• PC–01 and NHSN measures (CAUTI, CLABSI, SSI, CDI, MRSA).	• January 1, 2015–December 31, 2015.	• January 1, 2017–December 31, 2017.
Efficiency and Cost Reduction:		
• MSPB	January 1, 2015–December 31, 2015.	January 1, 2017–December 31, 2017.

* Previously adopted baseline and performance periods that remain unchanged (80 FR 49562 through 49563).

PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2020 PROGRAM YEAR

Domain	Baseline period	Performance period
Clinical Care:		
• Mortality (MORT–30–AMI, MORT–30–HF, MORT–30–PN) *	• July 1, 2010–June 30, 2013	• July 1, 2015–June 30, 2018.
• THA/TKA *	• July 1, 2010–June 30, 2013	• July 1, 2015–June 30, 2018.
Safety:		
• PSI 90 *	July 1, 2012–June 30, 2014	July 1, 2016–June 30, 2018.

* Previously adopted baseline and performance periods that remain unchanged (80 FR 49562 through 49563).

PREVIOUSLY ADOPTED AND NEWLY PROPOSED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2021 PROGRAM YEAR

Domain	Baseline period	Performance period
Clinical Care:		
• Mortality (MORT–30–AMI, MORT–30–HF, MORT–30–COPD) *	• July 1, 2011–June 30, 2014	• July 1, 2016–June 30, 2019.
• THA/TKA *	• April 1, 2011–March 31, 2014	• April 1, 2016–March 31, 2019.
• MORT–30–PN (updated cohort)	• July 1, 2012–June 30, 2015	• August 1, 2017–June 30, 2019.
Efficiency and Cost Reduction:		
• Payment (AMI Payment and HF Payment)	July 1, 2012 to June 30, 2015	July 1, 2017 to June 30, 2019.

* Previously adopted baseline and performance periods that remain unchanged (80 FR 49562 through 49563).

NEWLY PROPOSED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2022 PROGRAM YEAR

Domain	Baseline period	Performance period
Clinical Care:		
• Mortality (MORT–30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–CABG).	• July 1, 2012–June 30, 2015	• July 1, 2017–June 30, 2020.
• THA/TKA	• April 1, 2012–March 31, 2015	• April 1, 2017–March 31, 2020.
• MORT–30–PN (updated cohort)	• July 1, 2012–June 30, 2015	• August 1, 2017–June 30, 2020.
Efficiency and Cost Reduction:		
• Payment (AMI Payment, HF Payment)	July 1, 2012–June 30, 2015	July 1, 2017–June 30, 2020.

We are inviting public comments on these proposals.

7. Proposed Immediate Jeopardy Policy Changes

a. Background

Section 1886(o)(1)(C) of the Act states that the Hospital VBP Program applies to subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Act), but excludes from the definition of the term "hospital" with respect to a fiscal year a hospital "for which, during the performance period for such fiscal year, the Secretary has cited deficiencies that pose immediate jeopardy to the health or safety of patients."

In 42 CFR 412.160 of our Hospital VBP Program regulations, we define the term "Cited for deficiencies that pose immediate jeopardy" to mean that "during the applicable performance period, the Secretary cited the hospital for immediate jeopardy on at least two surveys using the Form CMS–2567, Statement of Deficiencies and Plan of Correction" (OMB Control Number 0938–0391). In 42 CFR 412.160, we also adopted the definition of "immediate jeopardy" found in 42 CFR 489.3 of our regulations.

Our current interpretation of the Hospital VBP Program's statute is that a hospital cited for deficiencies that pose immediate jeopardy during any part of the finalized performance period for the applicable program year does not meet the definition of the term "hospital," and thus is excluded from the Hospital VBP Program for that program year. Because the Hospital VBP Program currently uses measures with 12-month, 24-month, and 36-month performance periods, a hospital's immediate jeopardy citations could result in its exclusion from the Hospital VBP Program for multiple program years.

b. Proposed Increase of Immediate Jeopardy Citations From Two to Three Surveys

We are proposing to amend our regulations at 42 CFR 412.160 to change the definition of the term "Cited for deficiencies that pose immediate jeopardy" to increase the number of surveys on which a hospital must be cited for immediate jeopardy before being excluded from the Hospital VBP Program pursuant to section 1886(o)(1)(C) of the Act from two to three. In other words, we are proposing that a hospital must be cited on Form CMS–2567, Statement of Deficiencies and Plan of Correction, for immediate jeopardy on at least three surveys during the performance period in order to meet the standard for exclusion from the Hospital VBP Program under section 1886(o)(1)(C)(ii)(II) of the Act. Beginning on the effective date of this change, hospitals would be excluded from the Hospital VBP Program for a particular program year if, during the performance period for that fiscal year, they were cited three times by the Secretary for deficiencies that pose immediate jeopardy to the health or safety of patients.

Because we expect that the effective date of this change will be October 1, 2016 (the first day of the FY 2017 Hospital VBP program year), only hospitals that were cited three times during the performance period that applies to the FY 2017 program year would be excluded from the Hospital VBP Program. Hospitals that were, as of October 1, 2016, cited for immediate jeopardy on two surveys during the performance period that applies to the FY 2017 program year could participate in the Hospital VBP Program for the FY 2017 program year.

We are proposing this change to be more inclusive of hospitals and to ensure that we are not too quickly excluding a hospital from participation in the Hospital VBP Program. After reviewing the survey and certification data, we have determined that limiting exclusion to those hospitals that have been cited for immediate jeopardy three or more times during the applicable performance period, rather than two, would continue to appropriately exclude hospitals that are cited for jeopardizing patient safety while allowing hospitals with a lower number of immediate jeopardy citations over significantly longer performance periods to continue to participate in the Hospital VBP Program. Many immediate jeopardy citations involve systematic issues of patient safety, and we believe that hospitals that are, during the performance period, cited by the Secretary for three or more deficiencies that pose immediate jeopardy should be excluded from the Hospital VBP Program. This proposal would ensure that we continue to assure high quality care while being as inclusive of hospitals as possible.

c. EMTALA-Related Immediate Jeopardy Citations

Hospitals are often alerted to immediate jeopardy situations when a surveyor or team of surveyors is in the process of conducting a survey of compliance with the Medicare condition of participation (CoPs) at the hospital and identifies those situations that immediately jeopardize the health and safety of patients (77 FR 53610). Following the survey, the Form CMS–2567, Statement of Deficiencies and Plan of Correction, is sent to the hospital, which contains the survey findings, including any immediate jeopardy situations. For EMTALA-related immediate jeopardy situations, however, the CMS Regional Office determines whether there was an EMTALA violation after reviewing the State Survey Agency's report and an expert physician review's findings, and, if so, whether it constituted an immediate jeopardy (77 FR 53610). The CMS Regional Office then sends the Form CMS–2567 to the hospital. Currently, the Automated Survey Processing Environment (ASPEN) system, an electronic system that supports our survey and certification activity, catalogs deficient practices (that is, noncompliance) identified during a survey and generates the Form CMS–2567 that is sent to the hospital after the survey. The survey end date generated in ASPEN is currently used as the date for assignment of the immediate jeopardy citation to a particular performance period (77 FR 53613). The additional processes for EMTALA-related immediate jeopardy citations can result in significant notification delays to hospitals (often several months or longer).

In the case of EMTALA-related immediate jeopardy citations only, we are proposing to change our policy regarding the date of the immediate jeopardy citation for possible exclusion from the Hospital VBP Program from the survey end date generated in ASPEN to the date of CMS' final issuance of Form CMS–2567 to the hospital. Form CMS–2567 is not considered final until it is transmitted to the healthcare facility, either by the State Survey Agency, or, in all EMTALA cases and certain other cases, by the CMS Regional Office. The date of final issuance is also tracked in ASPEN. The date the Form CMS–2567 is sent by the CMS Regional Office to the hospital (via mail, electronically, or both) is the date of final issuance recorded in ASPEN. We believe this change would accurately reflect the date hospitals receive official notification of an immediate jeopardy citation based on the issuance date of Form CMS–2567 as this date will be weeks, if not months, after the survey end date. Hospitals may continue to receive preliminary notice during the onsite EMTALA investigation survey that they may receive an immediate jeopardy citation based on survey findings. However, because the decision-making responsibility in EMTALA investigations always rests with the CMS Regional Office, the final determination and notification of immediate jeopardy citations will always be delayed. The Form CMS–2567 constitutes the official notice to a healthcare facility of the survey findings.

Finally, in instances where one onsite hospital survey resulted in both hospital CoP immediate jeopardy citation(s) as well as EMTALA immediate jeopardy citation(s), the survey end date would be the default date for potential exclusion from the Hospital VBP Program. CMS recognizes the hospital will receive notification of the EMTALA immediate jeopardy citation(s) at a later date than the CoP immediate jeopardy citation(s). However, because the hospital was notified of the CoP immediate jeopardy citation(s) at the time of survey, this date will be used for the performance period for potential exclusion from the Hospital VBP Program. Even though there may be separate enforcement actions resulting from the same survey, we will consider each Form CMS–2567 with immediate jeopardy findings to be one citation for purposes of the Hospital VBP Program (77 FR 53613).

We are proposing to revise our regulations at 42 CFR 412.160 to reflect the above proposal and specify use of the date of CMS' issuance of Form CMS–2567 to the hospital for EMTALA immediate jeopardy citation(s). We also specify that in instances where one onsite hospital survey resulted in both hospital CoP immediate jeopardy citation(s) as well as EMTALA immediate jeopardy citation(s), the survey end date would be the date we use for purposes of assigning the citations to a performance period to determine whether the hospital should be excluded from the Hospital VBP Program for a particular program year.

We are inviting public comments on this proposal.

8. Proposed Performance Standards for the Hospital VBP Program

a. Background

Section 1886(o)(3)(A) of the Act requires the Secretary to establish performance standards for the measures selected under the Hospital VBP Program for a performance period for the applicable fiscal year. The performance standards must include levels of achievement and improvement, as required by section 1886(o)(3)(B) of the Act, and must be established no later than 60 days before the beginning of the performance period for the fiscal year involved, as required by section 1886(o)(3)(C) of the Act. We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) for further discussion of achievement and improvement standards under the Hospital VBP Program.

In addition, when establishing the performance standards, section 1886(o)(3)(D) of the Act requires the Secretary to consider appropriate factors, such as: (1) Practical experience with the measures, including whether a significant proportion of hospitals failed to meet the performance standard during previous performance periods; (2) historical performance standards; (3) improvement rates; and (4) the opportunity for continued improvement.

We refer readers to the FY 2013, FY 2014, and FY 2015 IPPS/LTCH PPS final rules (77 FR 53604 through 53605; 78 FR 50694 through 50698; and 79 FR 50077 through 50079) for a more detailed discussion of the general scoring methodology used in the Hospital VBP Program.

We note that the performance standards for the following measures are calculated with lower values representing better performance:

- The NHSN measures (the CLABSI, CAUTI, CDI and MRSA Bacteremia measures);
- The PSI 90 measure;
- The Colon and Abdominal Hysterectomy SSI measure;
- The THA/TKA measure;
- The MSPB measure; and,
- The proposed HF and AMI Payment measures.

This distinction is made in contrast to other measures for which higher values indicate better performance. As discussed further in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50684), the performance standards for the Colon and Abdominal Hysterectomy SSI measure are computed separately for each procedure stratum, and we will first award achievement and improvement points to each stratum separately, then compute a weighted average of the points awarded to each stratum by predicted infections.

b. Previously Adopted and Newly Proposed Performance Standards for the FY 2019 Program Year

In accordance with our finalized methodology for calculating performance standards (discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513)), we are proposing to adopt the following additional performance standards for the FY 2019 program year. We note that the numerical values for the performance standards displayed below represent estimates based on the most recently available data, and we intend to update the numerical values in the FY 2017 IPPS/LTCH PPS final rule. We note further that the MSPB measure's performance standards are based on performance period data; therefore, we are unable to provide numerical equivalents for the standards at this time.

PREVIOUSLY ADOPTED AND NEWLY PROPOSED PERFORMANCE STANDARDS FOR THE FY 2019 PROGRAM YEAR: SAFETY, CLINICAL CARE, AND EFFICIENCY AND COST REDUCTION MEASURES

Measure ID	Description	Achievement threshold	Benchmark
	Safety Measures		
CAUTI *	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure.	0.438000	0.000000.
CLABSI *	National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure.	0.465000	0.000000.
CDI *	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	0.823000	0.013000.
MRSA Bacteremia *	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	0.812000	0.000000.
PSI 90 * ±	Patient Safety for Selected Indicators (Composite Measure).	0.084034	0.058946.
Colon and Abdominal Hysterectomy SSI *.	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	• 0.856000 • 0.682000	• 0.000000. • 0.000000.
PC–01	Elective Delivery	0.012384	0.000000.
	Clinical Care Measures		
MORT–30–AMI ±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0.850671	0.873263.
MORT–30–HF ±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization.	0.883472	0.908094.
MORT–30–PN ±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.	0.882334	0.907906.

Previously Adopted and Newly Proposed Performance Standards for the FY 2019 Program Year: Safety, Clinical Care, and Efficiency and Cost Reduction Measures—Continued

Measure ID	Description	Achievement threshold	Benchmark
THA/TKA *±	Hospital-Level Risk-Standardized Complication Rate (RSMR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	0.032229	0.023178.
	Efficiency and Cost Reduction Measure		
MSPB *	Payment-Standardized Medicare Spending Per Beneficiary (MSPB).	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.
± Previously adopted performance standards.

In the past, we have used the "normalization" approach to scoring the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain (which we are proposing, in section IV.H.3.b. of the preamble of this proposed rule, to rename the Person and Community Engagement domain beginning with the FY 2019 program year). The nine dimensions of the HCAHPS measure, one of which is the CTM–3 measure, are calculated to generate the HCAHPS Base Score. For each of the nine dimensions, Achievement Points (0–10 points) and Improvement Points (0–9 points) are calculated, the larger of which is summed across the nine dimensions to create a prenormalized HCAHPS Base Score (0–90 points). The prenormalized HCAHPS Base Score is then multiplied by 8/9 (0.88888) and rounded according to standard rules (values of 0.5 and higher are rounded up, values below 0.5 are rounded down) to create the normalized HCAHPS Base Score. Each of the nine dimensions is of equal weight, so that the normalized HCAHPS Base Score would range from 0 to 80 points. HCAHPS Consistency Points are then calculated and range from 0 to 20 points. The Consistency Points now consider scores across all nine of the Person and Community Engagement dimensions. The final element of the scoring formula is the sum of the HCAHPS Base Score and the HCAHPS Consistency Points and will range from 0 to 100 points.

Proposed Performance Standards for the FY 2019 Program Year Proposed Person and Community Engagement Domain *

HCAHPS survey dimension	Floor (percent)	Achievement threshold (percent)	Benchmark (percent)
Communication with Nurses	16.32	78.59	86.81
Communication with Doctors	22.56	80.33	88.55
Responsiveness of Hospital Staff	21.91	65.00	80.27
Pain Management	16.02	70.04	78.60
Communication about Medicines	6.19	63.18	73.51
Hospital Cleanliness & Quietness	13.78	65.64	79.12
Discharge Information	60.58	86.88	91.73
3-Item Care Transition	4.26	51.35	62.73
Overall Rating of Hospital	30.52	70.58	84.68

* We are proposing, in section IV.H.3.b. of the preamble of this proposed rule, to change the name of this domain from Patient- and Caregiver-Centered Experience of Care/Care Coordination domain to Person and Community Engagement domain beginning with the FY 2019 program year.

We are inviting public comments on these proposed performance standards.

c. Previously Adopted Performance Standards for Certain Measures for the FY 2020 Program Year

As discussed above, we have adopted certain Safety and Clinical Care domain measures for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50062 through 50065), we adopted the PSI 90 measure in the Safety domain and the THA/TKA measure in the Clinical Care domain for the FY 2019 program year and subsequent years. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50077), we adopted performance standards for the MORT–30–AMI, MORT–30–HF, MORT–30–PN, and THA/TKA for the FY 2020 program year. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49566), we also adopted performance standards for the PSI–90 measure.

PREVIOUSLY ADOPTED PERFORMANCE STANDARDS FOR CERTAIN CLINICAL CARE DOMAIN AND SAFETY DOMAIN MEASURES FOR THE FY 2020 PROGRAM YEAR

Measure ID	Description	Achievement threshold	Benchmark
	Safety Domain		
PSI 90 *	Patient Safety for Selected Indicators (Composite Measure)	0.778761	0.545903
	Clinical Care Domain		
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0.853715	0.875869
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization.	0.881090	0.906068
MORT–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.	0.882266	0.909532
THA/TKA *	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	0.032229	0.023178

* Lower values represent better performance.

d. Previously Adopted and Newly Proposed Performance Standards for Certain Measures for the FY 2021 Program Year

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49567), we adopted performance standards for the FY 2021 program year for the Clinical Care domain measures (THA/TKA, MORT–30–HF, MORT–30–AMI, MORT–30–PN, and MORT–30–COPD). We are proposing to add two measures, AMI Payment and HF Payment, beginning with the FY 2021 program year. The previously adopted and proposed performance standards for these measures are set out below.

PREVIOUSLY ADOPTED AND PROPOSED PERFORMANCE STANDARDS FOR THE FY 2021 PROGRAM YEAR

Measure ID	Description	Achievement threshold	Benchmark
	Clinical Care Measures		
MORT–30–AMI ±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0.860355	0.879714.
MORT–30–HF ±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization.	0.883803	0.906144.
MORT–30–PN ±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.	0.886443	0.910670.
MORT–30–COPD ±	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	0.923253	0.938664.
THA/TKA *±	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	0.030890	0.022304.
	Efficiency and Cost Reduction Measures		
AMI Payment *#	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI).	Median Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.	Mean of the lowest decile Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.
HF Payment *#	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Heart Failure (HF).	Median Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.	Mean of the lowest decile Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.

± Previously adopted performance standards.

*Lower values represent better performance.
#Proposed to be scored the same as the MSPB measure.

e. Proposed Performance Standards for Certain Measures for the FY 2022 Program Year

We are proposing the following performance standards for the FY 2022 program year for the Clinical Care domain measures (THA/TKA, MORT–30–AMI, MORT–30–HF, MORT–30–PN, MORT–30–COPD), and the newly proposed MORT–30–CABG:

PROPOSED PERFORMANCE STANDARDS FOR THE FY 2022 PROGRAM YEAR

Measure ID	Description	Achievement threshold	Benchmark
	Clinical Care Measures		
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following (RSMR) Acute Myocardial Infarction (AMI) Hospitalization.	0.861793	0. 881305.
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization.	0.879869	0.903608.
MORT–30–PN (updated cohort).	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.	0.836122	0.870506.
MORT–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	0.920058	0.936962.
THA/TKA*	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	0.029599	0.021439.
MORT–30–CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery.	0.979000	0.968210.
	Efficiency and Cost Reduction Measures		
AMI Payment*#	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI).	Median Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period..	Mean of the lowest decile Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period
HF Payment*#	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Heart Failure (HF).	Median Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.	Mean of the lowest decile Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care across all hospitals during the performance period.

*Lower values represent better performance.
#Proposed to be scored the same as the MSPB measure.

9. FY 2019 Program Year Scoring Methodology

a. Domain Weighting for the FY 2019 Program Year for Hospitals That Receive a Score on All Domains

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49568 through 49570), we adopted equal weight of 25 percent for each of the four domains in the FY 2018 program year for hospitals that receive a score in all domains. For the FY 2019 program year, we are not proposing to remove any measures nor are we proposing to adopt any new measures. We also are not proposing any changes to the domain weighting for hospitals receiving a score on all domains.

DOMAIN WEIGHTS FOR THE FY 2019 PROGRAM YEAR FOR HOSPITALS RECEIVING A SCORE ON ALL DOMAINS

Domain	Weight (percent)
Safety	25
Clinical Care	25
Efficiency and Cost Reduction	25
Person and Community Engagement*	25

*We are proposing, in section IV.H.3.b. of the preamble of this proposed rule, to change the name of this domain from Patient- and Caregiver-Centered Experience of Care/Care Coordination domain to Person and Community Engagement domain beginning with the FY 2019 program year.

b. Domain Weighting for the FY 2019 Program Year and Future Years for Hospitals Receiving Scores on Fewer Than Four Domains

For the FY 2017 program year and subsequent years, we adopted a policy that hospitals must receive domain scores on at least three of four quality domains in order to receive a TPS, and hospitals with sufficient data on only three domains will have their TPSs proportionately reweighted (79 FR 50084 through 50085).

Under these policies, in order to receive a TPS for the FY 2019 program year and future years:

- Hospitals must report a minimum number of 100 completed HCAHPS surveys for a hospital to receive a Patient- and Caregiver-Centered Experience of Care/Care Coordination domain (which we are proposing, in section IV.H.3.b. of the preamble of this proposed rule, to rename the Person and Community Engagement domain beginning with the FY 2019 program year) score.
- Hospitals must meet the requirements to receive a MSPB measure score in order to receive an Efficiency and Cost Reduction domain score. Hospitals must report a minimum number of 25 cases for the MSPB measure (77 FR 53609 through 53610) and the AMI Payment and HF Payment measures.
- Hospitals must receive a minimum of two measure scores within the Clinical Care domain. Hospitals must report a minimum number of 25 cases for each of the mortality measures (77 FR 53609 through 53610) and the THA/TKA measure.
- Hospitals must receive a minimum of three measure scores within the Safety domain.

++ Hospitals must report a minimum of three cases for any underlying indicator for the PSI 90 measure based on AHRQ's measure methodology (77 FR 53608 through 53609).

++ Hospitals must report a minimum of one predicted infection for NHSN-based surveillance measures based on CDC's minimum case criteria (77 FR 53608 through 53609).

++ Hospitals must report a minimum of 10 cases for the PC–01 measure (76 FR 26530).

We are not proposing any changes to the minimum numbers of domain scores, cases, and measures outlined above. We continue to believe that these requirements appropriately balance our desire to enable as many hospitals as possible to participate in the Hospital VBP Program and the need for TPSs to be sufficiently reliable to provide meaningful distinctions between hospitals' performance on quality measures. We are inviting public comment on these proposals.

I. Proposed Changes to the Hospital-Acquired Condition (HAC) Reduction Program

1. Background

We refer readers to section V.I.1.a. of the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50708) for a general overview of the HAC Reduction Program.

2. Statutory Basis for the HAC Reduction Program

We refer readers to section V.I.2. of the FY 2014 IPPS/LTCH PPS final rule (78 FR 50708 through 50709) for a detailed discussion of the statutory basis of the HAC Reduction Program.

3. Overview of Previous HAC Reduction Program Rulemaking

For a further description of our policies for the HAC Reduction Program, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50729), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50087 through 50104) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49570 through 49581). These policies describe the general framework for implementation of the HAC Reduction Program, including: (a) The relevant definitions applicable to the program; (b) the payment adjustment under the program; (c) the measure selection and conditions for the program, including a risk-adjustment and scoring methodology; (d) performance scoring; (e) the process for making hospital-specific performance information available to the public, including the opportunity for a hospital to review the information and submit corrections; and (f) limitation of administrative and judicial review.

We also have codified certain requirements of the HAC Reduction Program at 42 CFR 412.170 through 412.172.

4. Implementation of the HAC Reduction Program for FY 2017

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), we finalized the following measures for use in the FY 2017 Program: PSI 90 measure for Domain 1 and the CDC NHSN measures CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI for Domain 2. We are not proposing any changes to this measure set for FY 2017. We also are not proposing to make any changes to the measures that were finalized for use in the FY 2016 program (CAUTI, CLABSI, and Colon and Abdominal Hysterectomy SSI) or the FY 2017 program (MRSA Bacteremia and CDI).

HAC REDUCTION PROGRAM MEASURES FOR FY 2017

Short name	Measure name	NQF No.
	Domain 1	
PSI 90	Patient Safety for Selected Indicators (Composite Measure)	0531

HAC REDUCTION PROGRAM MEASURES FOR FY 2017—Continued

Short name	Measure name	NQF No.
	Domain 2	
CAUTI	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	1717
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	1716

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), we finalized and codified at 42 CFR 412.170 a 2-year period during which we collect data used to calculate the Total HAC Score. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49574), we finalized the 2-year time periods for the calculation of HAC Reduction Program measure results for FY 2017. For the Domain 1 measure (PSI 90 measure), we will use the 24-month period from July 1, 2013 through June 30, 2015. The claims for all Medicare FFS beneficiaries discharged during this period would be included in the calculations of measure results for FY 2017. For the CDC NHSN measures previously finalized for use in the FY 2017 HAC Reduction Program (CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI), we will use data from CYs 2014 and 2015.

We also note that we anticipate we will be able to provide hospitals with their confidential hospital-specific reports and discharge level information used in the calculation of their FY 2017 Total HAC Score in late summer 2016 via the QualityNet Secure Portal.[54] In order to access their hospital-specific reports, hospitals must register for a QualityNet Secure Portal account. We did not make any changes to the review and correction policies for FY 2016. Hospitals have a period of 30 days after the information is posted to the QualityNet Secure Portal to review and submit corrections for the calculation of their HAC Reduction Program measure scores, domain scores, and Total HAC Score for the fiscal year.

For FY 2017, we are proposing updates to the following HAC Reduction Program policies: (1) A proposal to clarify data requirements for Domain 1; and (2) a proposal for NHSN CDC HAI data submission requirements for newly opened hospitals. Each policy is described in more detail below.

a. Clarification of Complete Data Requirements for Domain 1

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50722) we finalized our plan to use the PSI 90 measure for Domain 1. Because hospitals may not have complete data for every AHRQ indicator in the PSI 90 measure, we decided to use the same methodology used for the Hospital VBP Program to determine the minimum number of indicators with complete data to be included in the calculation of the Domain 1 measure. In addition, we finalized the following rules to determine the number of AHRQ indicators to be included in the calculation for a hospital's Domain 1 score. For Domain 1, we defined "complete data" as whether a hospital has enough eligible discharges to calculate a rate for a measure. In order to have complete data for the PSI 90 measure, a hospital must have three or more eligible discharges for at least one component indicator.

In establishing the performance period for the PSI 90 measure, we relied upon an analysis by Mathematica Policy Research, a CMS contractor, which found the measure was most reliable with a 24-month performance period. This analysis also indicated the measure was unreliable with a performance period of less than 12 months.[55] We have since determined that the current definition for "complete data" may result in facilities with less than 12 months of data being eligible to receive a score on the PSI 90 measure, and that the resulting score may not be reflective of the hospital's clinical performance. While the PSI 90 measure continues to play a vital role in patient safety and is an integral part of the HAC Reduction Program, we believe that reliable data is a critical component of accurately assessing hospital performance.

To address this concern, we are proposing to clarify the term "complete data" for the PSI 90 measure within Domain 1 to require that hospitals have three or more eligible discharges for at least one component indicator and 12 months or more of data to receive a Domain 1 score. Under this proposal, hospitals with less than 12 months of PSI 90 data would not receive a Domain 1 score, regardless of the number of eligible discharges at the hospital. If a hospital has 12 months or more of PSI 90 data, the hospital would have to have three or more eligible discharges for at least one component indicator to receive a Domain 1 score. We believe this is the most favorable method for scoring measure results for hospitals.

We believe, after weighing the considerations, that this additional policy should be incorporated into the HAC Reduction Program for FY 2017 and subsequent years, primarily because this approach greatly improves the measure's assessment of quality and, therefore, its implementation should not be unnecessarily delayed. This clarification would be a change to the Domain 1 criteria and would not change our current scoring policy for Domain 2. As previously finalized in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50722 through 50723), if a hospital does not have enough data to calculate the PSI 90 measure score for Domain 1 but has "complete data" for at least one measure in Domain 2, its Total HAC Score will depend entirely on its Domain 2 score. Similarly, if a hospital has "complete data" to calculate the PSI 90 measure score in Domain 1 but none of the measures in Domain 2, its Total HAC Score will be based entirely on its Domain 1 score. If a hospital does not have "complete data" to calculate the PSI 90 measure score for Domain 1 or any of the measures in Domain 2, we will not calculate a Total HAC Score for this hospital. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50722 through 50723) for a detailed discussion of Domain 2 scoring.

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[54] Available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetBasic&cid=1228773343598.*

[55] Mathematica Policy Research (November 2011). Reporting period and reliability of AHRQ, CMS 30-day and HAC Quality Measures—Revised. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf.*

We are inviting public comments on our proposal to require that hospitals have three or more eligible discharges for at least one component indicator and 12 months or more of data to receive a Domain 1 score beginning in the FY 2017 HAC Reduction Program.

b. Clarification of NHSN CDC HAI Data Submission Requirements for Newly Opened Hospitals

We have encountered issues with some newly opened hospitals that do not appear to understand that they must submit CDC NHSN HAI data for the HAC Reduction Program, even when they may not be required to report under the Hospital IQR Program. As set forth in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50098), a hospital that does not have an ICU waiver *or other waiver* for the CDC NHSN HAI measures and does not submit data will receive the maximum of 10 points for that measure. We noted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50723) that, for Domain 2, we will obtain measure results that hospitals submitted to the CDC NHSN from the Hospital IQR Program.[56] However, we note that participation in the Hospital IQR Program is voluntary, while participation in the HAC Reduction Program is mandatory for almost all IPPS hospitals (we refer readers to section 1886(d)(1)(B) of the Act; 42 CFR 412.170 (definition of the term "applicable hospital"); and 42 CFR 412.172(e)). The HAC Reduction Program does not apply to hospitals and hospital units that are excluded from the IPPS, such as LTCHs, cancer hospitals, children's hospitals, IRFs, IPFs, CAHs, and Puerto Rico hospitals (79 FR 50087 through 50088).

We believe that it is important to establish data submission requirements for all applicable hospitals under the HAC Reduction Program. We are proposing the following requirements for newly opened hospitals for CDC NHSN HAI data submissions. We note that these requirements do not affect any requirements for facilities in States that are required by law to report HAI data to NHSN.

- If a hospital files a notice of participation (NOP) with the Hospital IQR Program within 6 months of opening, the hospital would be required to begin submitting data for the CDC NHSN HAI measures no later than the first day of the quarter following the NOP.
- If a hospital does not file a NOP with the Hospital IQR Program within 6 months of opening, the hospital would be required to begin submitting data for the CDC NHSN HAI measures on the first day of the quarter following the end of the 6-month period to file the NOP.

For example, if a subsection (d) hospital opens on January 1 and it intends to participate in the Hospital IQR Program, the hospital would be required to file a Hospital IQR Program NOP no later than July 1, and begin submitting data to NHSN no later than October 1. If a subsection (d) hospital opens on January 1 and it does not intend to participate in the Hospital IQR Program (that is, no NOP is filed), it must begin submitting data to NHSN no later than July 1 of that year. We believe that these data submission requirements are clear, align with the Hospital IQR Program, and are fair and equitable for all newly opened hospitals. Hospitals that are not required to submit data within the respective HAC Reduction Program year will not receive a score. These hospitals will receive a designation of "NEW," and will not receive any points for CDC NHSN HAI measures.

We further note that this clarification does not affect the narrative rules used in calculation of the Domain 2 Score. We will continue to follow all Domain 2 scoring procedures as previously finalized, and we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49575) for further discussion of the narrative rules used in calculation of the Domain 2 Score. We believe that this proposal should be incorporated into the HAC Reduction Program for FY 2017 and subsequent years.

We are inviting public comments on our proposal to adopt these policies related to the data submission requirements beginning in the FY 2017 HAC Reduction Program.

5. Implementation of the HAC Reduction Program for FY 2018

For FY 2018, we are proposing the following HAC Reduction Program policies: (1) Adoption of the modified version of the NQF-endorsed PSI 90: Patient Safety and Adverse Events Composite; (2) defining the applicable time periods for the FY 2018 HAC Reduction Program and the FY 2019 HAC Reduction Program; (3) changes to the scoring methodology; and (4) a request for comments on additional measures for potential future adoption.

a. Proposed Adoption of Modified PSI 90: Patient Safety and Adverse Events Composite (NQF #0531)

(1) Background

We are proposing to adopt refinements to the Agency for Healthcare Research and Quality (AHRQ) Patient Safety and Adverse Events Composite (NQF #0531) for the HAC Reduction Program beginning with the FY 2018 payment determination and subsequent years. In summary, the PSI 90 measure was refined to reflect the relative importance and harm associated with each component indicator to provide a more reliable and valid signal of patient safety events. We believe refining PSI 90 will provide strong incentives for hospitals to ensure that patients are not harmed by the medical care they receive, a critical consideration in quality improvement.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50712 through 50717), we adopted the PSI 90 measure (NQF #0531) in the HAC Reduction Program as an important measure of patient safety and adverse events. As previously adopted, PSI 90 consisted of eight component indicators: (1) PSI 3 Pressure Ulcer Rate; (2) PSI 6 Iatrogenic Pneumothorax Rate; (3) PSI 7 Central Venous Catheter-Related Blood Stream Infections Rate; (4) PSI 8 Postoperative Hip Fracture Rate; (5) PSI 12 Perioperative Pulmonary Embolism/Deep Vein Thrombosis Rate; (6) PSI 13 Postoperative Sepsis Rate; (7) PSI 14 Postoperative Wound Dehiscence Rate; and (8) PSI 15 Accidental Puncture and Laceration Rate.[57]

The currently adopted eight-indicator version of the measure underwent extended NQF maintenance reendorsement in the 2014 NQF Patient Safety Committee due to concerns with the underlying component indicators and their composite weights. In the NQF-Endorsed Measures for Patient Safety, Final Report,[58] the NQF Patient Safety Committee deferred its final decision for the PSI 90 measure until the following measure evaluation cycle. In the meantime, AHRQ worked to address many of the NQF stakeholders' concerns about PSI 90, which subsequently completed NQF maintenance re-review and received reendorsement on December 10, 2015.

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[56] For a further discussion of CDC NHSN HAI Data submission requirements for the Hospital IQR Program, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53536) and 42 CFR 412.140(a)(3)(i) and 412.140(b).

[57] NQF-Endorsed Measures for Patient Safety, Final Report. Available at: *http://www.qualityforum.org/Publications/2015/01/NQF-Endorsed_Measures_for_Patient_Safety_Final_Report.aspx.*

[58] NQF-Endorsed Measures for Patient Safety, Final Report available at: *http://www.qualityforum.org/Publications/2015/01/NQF-Endorsed_Measures_for_Patient_Safety,_Final_Report.aspx.*

The PSI 90 measure's extended NQF reendorsement led to several changes to the measure.[59] First, the name of the PSI 90 measure has changed to "Patient Safety and Adverse Events Composite" (NQF #0531) (herein referred to as the "modified PSI 90"). Second, the modified PSI 90 measure includes the addition of three indicators: (1) PSI 09 Perioperative Hemorrhage or Hematoma Rate; (2) PSI 10 Physiologic and Metabolic Derangement Rate; and (3) PSI 11 Postoperative Respiratory Failure Rate. Third, PSI 12 Perioperative Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT) Rate and PSI 15 Accidental Puncture or Laceration Rate have been respecified in the modified PSI 90. Fourth, PSI 07 Central Venous Catheter-Related Blood Stream Infection Rate has been removed in the modified PSI 90. Fifth, the weighting of component indicators in the modified PSI 90 is based not only on the volume of each of the patient safety and adverse events, but also the harms associated with the events.

We consider these changes to the modified PSI 90 to be substantive changes to the measure. Therefore, we are proposing to adopt the modified PSI 90 for the HAC Reduction Program beginning with the FY 2018 payment determination and subsequent years. We explain the modified PSI 90 more fully below, and also refer readers to the measure description on the NQF Web site at: *https://www.qualityforum.org/QPS/MeasureDetails.aspx?standardID=321&print=0&entityTypeID=3.*

We note that the proposed modified PSI 90 (MUC15–604) was included on a publicly available document entitled "2015 Measures Under Consideration for December 1, 2015"[60] in compliance with section 1890A(a)(2) of the Act, and was reviewed by the MAP. The MAP supported this measure, stating that "the PSI measures were developed to identify harmful healthcare related events that are potentially preventable. Three additional PSIs have been added to this updated version of the measure. PSIs were better linked to important changes in clinical status with 'harm weights' that are based on diagnoses that were assigned after the complication. This is intended to allow the measure to more accurately reflect the impact of the events."[61] The measure received support for inclusion in the HAC Reduction Program as referenced in the MAP Final Recommendations Report.[62]

(2) Overview of the Measure Changes

First, the name of the PSI 90 measure has changed from the "Patient Safety for Selected Indicators Composite Measure" to the "Patient Safety and Adverse Events Composite" (NQF #0531) to more accurately capture the indicators included in the measure.

Second, the PSI 90 measure has expanded from 8 to 10 component indicators. The modified PSI 90 is a weighted average of the following 10 risk-adjusted and reliability-adjusted individual component PSI rates:

- PSI 03 Pressure Ulcer Rate;
- PSI 06 Iatrogenic Pneumothorax Rate;
- PSI 08 Postoperative Hip Fracture Rate;
- PSI 09 Postoperative Hemorrhage or Hematoma Rate;*
- PSI 10 Physiologic and Metabolic Derangement Rate;*
- PSI 11 Postoperative Respiratory Failure Rate;*
- PSI 12 Perioperative Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT) Rate;
- PSI 13 Postoperative Sepsis Rate,
- PSI 14 Postoperative Wound Dehiscence Rate; and
- PSI 15 Accidental Puncture or Laceration Rate.[63]

(* Denotes new component for the modified PSI 90 measure.)

As stated above, the modified PSI 90 measure also removed PSI 07, Central Venous Catheter-Related Blood Stream Infection Rate, because of potential overlap with the CLABSI measure (NQF #0139) which has been included in the Hospital IQR Program since the FY 2011 IPPS/LTCH PPS final rule (75 FR 50201 through 50202), the HAC Reduction Program since the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), and the Hospital VBP Program since the FY 2013 IPPS/LTCH PPS final rule (77 FR 53597 through 53598).

In response to stakeholder concerns, highlighted in the NQF 2014 Patient Safety Report,[64] the modified PSI 90 also respecified two component indicators, PSI 12 and PSI 15. Specifically, for PSI 12 Perioperative PE or DVT rate, the NQF received public comments concerning the inclusion of: (1) Extracorporeal membrane oxygenation (ECMO) procedures in the denominator; and (2) intra-hospital variability in the documentation of calf vein thromboses (which have uncertain clinical significance). As such, the revised PSI 12 component indicator no longer includes ECMO procedures in the denominator or isolated deep vein thrombosis of the calf veins in the numerator. PSI 15 was also respecified further to focus on the most serious intraoperative injuries—those that were unrecognized until they required a subsequent reparative procedure. The modified denominator of PSI 15 now is limited to discharges with an abdominal/pelvic operation, rather than including all medical and surgical discharges. In addition, to identify events that are more likely to be clinically significant and preventable, the PSI 15 numerator was modified to require both: (1) A diagnosis of an accidental puncture and/or laceration; and (2) an abdominal/pelvic reoperation one or more days after the index surgery.

Finally, the NQF Patient Safety Review Committee raised concerns about the weighting scheme of the component indicators. In prior versions of the measure, the weights of each component PSI were based solely on volume (numerator rates). In the modified PSI 90, the rates of each component PSI are weighted based on statistical and empirical analyses of volume, excess clinical harm associated with the PSI, and disutility (individual preference for a health state linked to a harm, such as death or disability). The final weight for each component indicator is the product of harm weights and volume weights (numerator weights). Harm weights are calculated by multiplying empirical estimates of excess harms associated with the patient safety event by utility weights linked to each of the harms. Excess harms are estimated using statistical models comparing patients with a safety event to those without a safety event in a Medicare FFS sample. Volume weights are calculated based on the number of safety events for the component indicators in an all-payer reference population.

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[59] National Quality Forum QPS Measure Description for "Patient Safety for Selected Indicators (modified version of PSI90) (Composite measure)" found at: *https://www.qualityforum.org/QPS/MeasureDetails.aspx?standardID=321&print=0&entityTypeID=3.*

[60] 2015 Measures Under Consideration List available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367.*

[61] MAP Final Recommendations available at: *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_Hospitals.aspx.*

[62] Ibid.

[63] *http://www.qualityforum.org/QPS/0531.*

[64] NQF Endorsed Measures for Patient Safety, Final Report. Available at: *http://www.qualityforum.org/Publications/2015/01/NQF-Endorsed_Measures_for_Patient_Safety,_Final_Report.aspx.*

For more information on the modified PSI 90 measure and component indicators, we refer readers to the Quality Indicator Empirical Methods available online at: *www.qualityindicators.ahrq.gov.*

(3) Risk Adjustment

The risk adjustment and statistical modeling approaches of the models remain unchanged in the modified PSI 90. In summary, the predicted value for each case is computed using a modeling approach that includes, but is not limited to, applying a Generalized Estimating Equation (GEE) hierarchical model (logistic regression with hospital random effect) and covariates for gender, age, Modified MS–DRG (MDRG), Major Diagnostic Category, transfer in, point of origin not available, procedure days not available, and AHRQ comorbidity (COMORB).

The expected rate for each of the indicators is computed as the sum of the predicted value for each case divided by the number of cases for the unit of analysis of interest (that is, hospital). The risk-adjusted rate for each of the indicators is computed using indirect standardization as the observed rate divided by the expected rate, multiplied by the reference population rate. For more details about risk adjustment, we refer readers to: *http://www.qualityindicators.ahrq.gov/Downloads/Resources/Publications/2015/Empirical_Methods_2015.pdf.*

(4) Adoption of the NQF-Endorsed Version of the Modified PSI 90

In summary, the PSI 90 measure was revised to reflect the relative importance and harm associated with each component indicator to provide a more reliable and valid signal of patient safety events. We believe that adopting the modified PSI 90 would continue to provide strong incentives for hospitals to ensure that patients are not harmed by the medical care they receive, which is a critical consideration in quality improvement. We are proposing to adopt the modified PSI 90 for the HAC Reduction Program for FY 2018 and subsequent years. We will continue to use the currently adopted eight-indicator version of the PSI 90 measure for the HAC Reduction Program for FY 2017. We are inviting public comment on our proposal to adopt the modified PSI 90 measure (NQF #0531) for the HAC Reduction Program for FY 2018.

b. Applicable Time Periods for the FY 2018 HAC Reduction Program and the FY 2019 HAC Reduction Program

Section 1886(p)(4) of the Act gives the Secretary the statutory authority to determine the applicable period for the HAC Reduction Program. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), we finalized and codified at 42 CFR 412.170 that we would use a 2-year time period of performance data to calculate the Total HAC Score. We believe the 24-month performance period provides hospitals and the public with the most current data available, while allowing sufficient time to complete the complex calculation process for these measures. The 24-month performance period was chosen because it tended to show that between 50 to 90 percent of hospitals attained a moderate or high level of reliability for AHRQ measures (78 FR 50717). Although we believe the 24-month time is the preferred length of time for performance data, there may be situations, discussed in more detail below, where the collection of 24 months of data is not operationally feasible.

Therefore, we are proposing, beginning in FY 2017 and for subsequent years, to permit flexibility to use a period other the 2 years from which data are collected in order to calculate the Total HAC Score under the HAC Reduction Program. We also are proposing to change the definition of "applicable period," in 42 CFR 412.170, to reflect this proposed change.

Since the ICD–10 transition was implemented on October 1, 2015, we have been monitoring our systems and so far claims are processing normally. The measure steward, AHRQ, has been reviewing the measure for any potential issues related to the conversion of approximately 70,000 ICD–10 coded operating room procedures[65] (*https://www.cms.gov/icd10manual/fullcode_cms/P1616.html*), which could directly affect the modified PSI 90 component indicators. In addition, to meet program requirements and implementation schedules, our system would require an ICD–10 risk-adjusted version of the AHRQ QI PSI software[66] by December 2016 for the FY 2018 payment determination year. At this time, a risk-adjusted ICD–10 version of the PSI 90 Patient Safety and Adverse Events Composite software is not expected to be available until late CY 2017.

To address these issues, for the current Domain 1 measure (PSI 90 Patient Safety and Adverse Events Composite), we are proposing to use the 15-month performance period from July 1, 2014 through September 30, 2015, for the FY 2018 HAC Reduction Program. This 15-month performance period would utilize only ICD–9–CM data and only apply to the FY 2018 payment year. The claims for all Medicare FFS beneficiaries discharged during this period would be included in the calculations of measure results for FY 2018. For the FY 2019 HAC Reduction Program, we are proposing to use the 21-month performance period from October 1, 2015 through September 30, 2017. This 21-month performance period would utilize only ICD–10 data and only apply to the FY 2019 payment year. The claims for all Medicare FFS beneficiaries discharged during this period would be included in the calculations of measure results for FY 2019.

Prior to deciding to propose abbreviated data collection periods for the FY 2018 and the FY 2019 payment determinations, we took several factors into consideration. These included the recommendations of the measure steward, the feasibility of using a combination of ICD–9 and ICD–10 data, minimizing provider burden, program implementation timelines, and the reliability of using shortened data collection periods, as well as the importance of continuing to publicly report this measure. We believe that using a 15-month data collection period for FY 2018 and a 21-month data collection period for FY 2019 best serve the need to provide important information on hospital patient safety and adverse events by allowing sufficient time to process the claims data and calculate the measures, while minimizing reporting burden and program disruption.

Because this issue only impacts the PSI 90 Patient Safety and Adverse Events Composite in Domain 1, for the CDC NHSN measures previously finalized for use in the FY 2017 HAC Reduction Program (CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI), we would use the 24-month performance period from January 1, 2015 through December 31, 2016 (CYs 2015 and 2016) for the FY 2018 HAC Reduction Program. For the FY 2019 HAC Reduction Program, we are proposing to use the 24-month performance period from January 1, 2016 through December 31, 2017 (CYs 2016 and 2017).

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[65] International Classification of Diseases, (ICD–10–CM/PCS) Transition—Background. Available at: *http://www.cdc.gov/nchs/icd/icd10cm_pcs_background.htm.*

[66] The AHRQ QI Software is the software used to calculate PSIs and the composite measure. More information is available at: *http://www.qualityindicators.ahrq.gov/Downloads/Resources/Publications/2015/Empirical_Methods_2015.pdf.*

We believe that using a 15-month period and a 21-month performance period for Domain 1 and a 24-month performance period for Domain 2 balance the needs of the HAC Reduction Program and allow sufficient time to process the claims data and calculate the measures. We will continue to test ICD–10 data that are submitted in order to ensure the accuracy of measure calculations and to monitor and assess the translation of measure specifications to ICD–10, potential coding variation, and impacts on measure performance and payment incentive programs.

We are inviting public comment on the proposals to update the definition of "applicable period" codified at 42 CFR 412.170 for FY 2017 and subsequent years and to use these updated performance periods for calculation of measure results for the FY 2018 and the FY 2019 HAC Reduction Programs.

c. Proposed Changes to the HAC Reduction Program Scoring Methodology

(1) Current Scoring Policy

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50721), we finalized a scoring methodology that aligns with the achievement scoring methodology currently used in the Hospital VBP Program. Our intent was to reduce confusion associated with multiple scoring methodologies by aligning the scoring for the Hospital VBP Program and the HAC Reduction Program. We note that alignment benefits the hospital stakeholders who have prior experience with the Hospital VBP Program. Accordingly, we implemented a methodology for assessing the top quartile of applicable hospitals for HACs based on performance standards.

We indicated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50720 through 50725) that points will be assigned to hospitals' performance for each measure. We finalized a decile-based methodology for assigning points, depending on the specific measures.

- For Domain 1, point assignment is based on a hospital's score for the PSI 90 measure.
- For the Domain 1 score, 1 to 10 points are assigned to the hospital.
- For the measures in Domain 2, point assignment for each measure is based on the SIR for that measure.
- For each SIR, 1 to 10 points are assigned to the hospital for each measure.
- The Domain 2 score consists of the average of points assigned to each measure.

To calculate a Total HAC Score for each hospital, we multiply each domain score by a weighting and add together the weighted domain scores to determine the Total HAC Score (§ 412.172(e)(3)). We use each hospital's Total HAC Score to determine the top quartile of subsection (d) hospitals that are subject to the payment adjustment beginning with discharges on or after October 1, 2014.

(2) Program Evaluation Efforts

As part of our ongoing efforts to evaluate the HAC Reduction Program, we recently conducted a review of our scoring methodology and assessed opportunities to strengthen the program. As part of that review, our Hospital Quality Reporting Program Support (HQRPS) contractors convened a technical expert panel (TEP) on October 19–20, 2015, with a follow-up call on December 11, 2015. The TEP examined multiple areas of the HAC Reduction Program and focused on identifying a scoring methodology that provides an incentive to hospitals to reduce HACs and distinguishes top performers from low performers. The TEP identified concerns with the current decile-based scoring methodology that included: Ties at the penalty threshold; hospitals with a limited amount of data being identified as poor performers; and situations in which hospitals with no adverse events and no Domain 2 data nonetheless become eligible for penalty.

During the FY 2016 HAC Reduction Program, a small subset of hospitals that had zero adverse events in Domain 1 and no Domain 2 score were identified as part of the worst-performing quartile. These hospitals received Domain 1 scores of 7.0, meaning they were in the 7th decile of hospitals for the PSI 90 measure despite being close to the PSI 90 measure mean value. As this subset of hospitals had no Domain 2 scores, they received a Total HAC Score equal to their Domain 1 score of 7.0. This Total HAC Score was greater than the 75th percentile cutoff for penalty determination of 6.75. CMS waived the penalty for these zero adverse event hospitals so they would not be treated as poor performers. These hospitals were potentially disadvantaged because their Total HAC Scores were determined solely on their Domain 1 Score. Because Domain 2 scores tend to be lower on average than Domain 1 scores,[67] other hospitals without Domain 2 scores are potentially treated the same as low performers in the same decile.

In addition, scoring using deciles can make it more difficult to distinguish top performers from low performers by creating a large number of ties on measure scores. For example, two hospitals with meaningfully different measure results may fall into the same decile bin and therefore be ultimately indistinguishable under the current scoring methodology. Conversely, two hospitals with performance that is not statistically distinguishable may fall into different decile bins. Furthermore, ties at the penalty threshold complicate the adjudication of payment adjustments; in both the FY 2015 and FY 2016 programs, less than 25 percent of all hospitals had Total HAC Scores above the threshold for penalties. Specifically, only 21.9 percent of hospitals in FY 2015 and 23.7 percent of hospitals in FY 2016 were subject to a payment adjustment.

To address stakeholder concerns regarding the current scoring methodology, we evaluated a number of alternatives and recommendations from the TEP. We refer readers to the Project Title: Hospital-Acquired Condition (HAC) Reduction Program Scoring Methodology Reevaluation located at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/TechnicalExpertPanels.html* for a summary of the TEP's discussion. These alternatives included replacement of the current decile-based scoring approach with the use of Winsorized[68] z-scores.

(3) Winsorized Z-Score Method

The Winsorized z-score method (z-score) uses a continuous measure score rather than forcing measure results into deciles. Z-scores represent a hospital's distance from the national mean for a measure in units of standard deviations. Under the z-score approach, poor-performing hospitals earn a positive z-score, reflecting measure values above the national mean, and better-performing hospitals earn a negative z-score, reflecting measure values below the national mean. For each measure, a hospital's z-score is based on the following equation that expresses the hospital's measure value minus the average value for that measure, divided by the standard deviation of the measure values across all hospitals:

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[67] This is because hospitals are assigned the minimum of one point for any measure for which they have a measure result of zero. For example, for the CAUTI measure, if 13 percent of hospitals have an SIR of zero, one point is assigned to each of these hospitals, even though the decile approach is intended to assign 10 percent of hospitals to each decile. Two points would be assigned to the remaining seven percent of hospitals that would fall in the second decile. This phenomenon does not affect Domain 1 scores, since the reliability-adjusted PSI 90 measure result is not equal to zero in any hospital.

[68] Winsorized measure results are truncated to the 5th and 95th percentiles, replacing values between the minimum and the 5th percentile with the 5th percentile value and replacing values between the 95th percentile and the maximum with the 95th percentile value. Z-scores are then calculated based on these values.

$$\text{Z-Score} = \frac{\text{(Hospital's Measure Performance} - \text{Mean Performance for All Hospitals)}}{\text{Standard Deviation for All Hospitals}}$$

To form the Total HAC Score, we would use the z-scores as hospitals' measure scores. In accordance with the current scoring methodology, we would then average the z-scores across measures within Domain 2 and assign the z-score for PSI 90 for Domain 1 to determine the domain scores. We would then multiply each domain score by the appropriate weighting and add together the weighted domain scores to determine the Total HAC Score. We would use each hospital's Total HAC Score to determine the top quartile of subsection (d) hospitals that are subject to the payment adjustment.

(4) Impact and Implementation

This z-score approach is straightforward to implement, easily adapted as measures are added or removed from the HAC Reduction Program, transparent, and familiar to a wide range of stakeholders. Continuous values address the limitations of decile scoring and preserve the magnitude of differences among hospitals' measure results. Thus, hospitals that differ meaningfully on their measure results will also differ meaningfully on their Total HAC Scores. Unlike the decile approach, continuous measure scores would substantially reduce ties of Total HAC Scores, which have prevented CMS from penalizing exactly 25 percent of hospitals in previous program years. The use of z-scores also improves alignment between Domains 1 and 2 and creates a more level playing field for hospitals with data in only Domain 1.

Based on FY 2016 data supplemented with MRSA Bacteremia and CDI results,[69] the z-score approach affects the penalty status of slightly more than 200 hospitals, relative to the decile approach. This approach brings 114 hospitals into the penalty zone and 103 hospitals out of the penalty zone and reduces the HAC Reduction Program's impact on the largest and smallest hospitals. Most importantly, because of the improvements in precision and standardization gained by implementing this approach, there is no penalization of hospitals that had zero adverse events and no Domain 2 score in either the actual results from FY 2016 or in the results based on the FY 2016 data supplemented with MRSA Bacteremia and CDI results.

Among the 184 hospitals with fewer than 25 beds, the proportion of hospitals penalized would fall from 33 percent to 18 percent. Among the 213 hospitals with more than 500 beds, the proportion of hospitals penalized would fall from 50 percent to 42 percent. The approach leaves the proportion of teaching, urban, and high-DSH hospitals penalized largely unchanged, with one exception. The z-score approach slightly increases the penalization rate among moderately high (50 to 64 percent) DSH hospitals, from 28 percent to 35 percent. Only 172 hospitals fall into this group; therefore, the increase reflects only 11 additional hospitals in that group being penalized.

We believe that differences in performance scores must reflect true differences in performance. In addition, hospitals must be able to clearly understand performance scoring methods and performance expectations to maximize their quality improvement efforts. Therefore, we are inviting public comments on our proposal to adopt the z-score method for calculating measure results beginning in the FY 2018 HAC Reduction Program.

6. Request for Comments on Additional Measures for Potential Future Adoption

We view the addition of other quality measures as a critical component of value-based purchasing, and we are seeking public comments on what additional measures we should consider adopting in the future. We believe that our continued efforts to reduce HACs are vital to improving patients' quality of care and reducing complications and mortality, while simultaneously decreasing costs. The reduction of HACs is an important marker of quality of care and has a positive impact on both patient outcomes and cost of care. Our goal for the HAC Reduction Program is to heighten the awareness of HACs and reduce the number of incidences that occur. We seek to adopt measures for the HAC Reduction Program that promote better, safer, and more efficient care. Our overarching purpose is to support the NQS' three-part aim of better health care for individuals, better health for populations, and lower costs for health care.

To the extent practicable, all HAC Reduction Program measures should be nationally endorsed by a multi-stakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures. Measures should take into account widely accepted criteria established in medical literature. We note that all measures proposed for the HAC Reduction Program should follow the criteria established by the DRA of 2005 in that they consist of high-volume or high-cost conditions that could be prevented by the use of evidence-based guidelines.

We welcome public comment and suggestions for additional HAC Reduction Program measures that will help achieve the Program goals in these or other measurement areas.

7. Maintenance of Technical Specifications for Quality Measures

Technical specifications for AHRQ's PSI–90 measure in Domain 1 can be found at AHRQ's Web site at: *http://qualityindicators.ahrq.gov/Modules/PSI_TechSpec.aspx*. Technical specifications for the CDC NHSN HAI measures in Domain 2 can be found at CDC's NHSN Web site at: *http://www.cdc.gov/nhsn/acute-care-hospital/index.html*. Both Web sites provide measure updates and other information necessary to guide hospitals participating in the collection of HAC Reduction Program data.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50100), we described a policy under which we use a subregulatory process to make nonsubstantive updates to measures used for the HAC Reduction Program. We are not proposing any changes to this policy at this time.

8. Extraordinary Circumstance Exception Policy for the HAC Reduction Program Beginning in FY 2016 and for Subsequent Years

We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49579 through 49581) for a detailed discussion of the exception policy for hospitals located in areas that experience disasters or other extraordinary circumstances for the HAC Reduction

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[69] Results are a based on actual FY 2016 measure data with the addition of MRSA Bacteremia and CDI data for the reporting period spanning October 2012 through December 2014.

Program. We are not proposing any changes to this policy for FY 2017.

J. Payment for Graduate Medical Education (GME) and Indirect Medical Education (IME) Costs (§§ 412.105, 413.75 Through 413.83)

1. Background

Section 1886(h) of the Act, as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. L. 99–272) and as currently implemented in the regulations at 42 CFR 413.75 through 413.83, establishes a methodology for determining payments to hospitals for the direct costs of approved graduate medical education (GME) programs. Section 1886(h)(2) of the Act sets forth a methodology for the determination of a hospital-specific base-period per resident amount (PRA) that is calculated by dividing a hospital's allowable direct costs of GME in a base period by its number of full-time equivalent (FTE) residents in the base period. The base period is, for most hospitals, the hospital's cost reporting period beginning in FY 1984 (that is, October 1, 1983 through September 30, 1984). The base year PRA is updated annually for inflation. In general, Medicare direct GME payments are calculated by multiplying the hospital's updated PRA by the weighted number of FTE residents working in all areas of the hospital complex (and at nonprovider sites, when applicable), and the hospital's Medicare share of total inpatient days.

Section 1886(d)(5)(B) of the Act provides for a payment adjustment known as the indirect medical education (IME) adjustment under the IPPS for hospitals that have residents in an approved GME program, in order to account for the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The regulations regarding the calculation of this additional payment are located at 42 CFR 412.105. The hospital's IME adjustment applied to the DRG payments is calculated based on the ratio of the hospital's number of FTE residents training in either the inpatient or outpatient departments of the IPPS hospital to the number of inpatient hospital beds.

The calculation of both direct GME payments and the IME payment adjustment is affected by the number of FTE residents that a hospital is allowed to count. Generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare direct GME and IME payments the hospital will receive. In an attempt to end the implicit incentive for hospitals to increase the number of FTE residents, Congress, through the Balanced Budget Act of 1997 (Pub. L. 105–33), established a limit on the number of allopathic and osteopathic residents that a hospital may include in its FTE resident count for direct GME and IME payment purposes. Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of residents for purposes of direct GME may not exceed the hospital's unweighted FTE count for direct GME in its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit based on the FTE count for IME during that cost reporting period is applied, effective for discharges occurring on or after October 1, 1997. Dental and podiatric residents are not included in this statutorily mandated cap.

The Affordable Care Act made a number of statutory changes relating to the determination of a hospital's FTE resident limit for direct GME and IME payment purposes and the manner in which FTE resident limits are calculated and applied to hospitals under certain circumstances.

Section 5503(a)(4) of the Affordable Care Act added a new section 1886(h)(8) to the Act to provide for the reduction in FTE resident caps for direct GME under Medicare for certain hospitals training fewer residents than their caps, and to authorize the redistribution of the estimated number of excess FTE resident slots to other qualified hospitals. In addition, section 5503(b) amended section 1886(d)(5)(B)(v) of the Act to require the application of the section 1886(h)(8) of the Act provisions in the same manner to the IME FTE resident caps. The policy implementing section 5503 of the Affordable Care Act was included in the November 24, 2010 final rule with comment period (75 FR 72147 through 72212) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53424 through 53434). Section 5506(a) of the Affordable Care Act amended section 1886(h)(4)(H) of the Act to add a new clause (vi) that instructs the Secretary to establish a process by regulation under which, in the event a teaching hospital closes, the Secretary will permanently increase the FTE resident caps for hospitals that meet certain criteria up to the number of the closed hospital's FTE resident caps. The policy implementing section 5506 of the Affordable Care Act was included in the November 24, 2010 final rule with comment period (75 FR 72212 through 72238) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53434 through 53448).

2. Change in New Program Growth From 3 Years to 5 Years

a. Urban and Rural Hospitals

Section 1886(h)(4)(H)(i) of the Act requires CMS to establish rules for calculating the direct GME caps of teaching hospitals training residents in new programs established on or after January 1, 1995. Under section 1886(d)(5)(B)(viii) of the Act, these rules also apply to the establishment of a hospital's IME cap. CMS implemented these statutory requirements in the August 29, 1997 **Federal Register** (62 FR 46005) and in the May 12, 1998 **Federal Register** (63 FR 26333). Generally, when CMS (then HCFA) implemented the regulations at 42 CFR 413.79(e)(1) and 42 CFR 412.105(f)(1)(vii), these regulations provided that if a hospital did not train any allopathic or osteopathic residents in its most recent cost reporting period ending on or before December 31, 1996, and it begins to participate in training residents in a new residency program (allopathic or osteopathic) on or after January 1, 1995, the hospital's unweighted FTE resident cap (which would otherwise be zero) may be adjusted based on the sum of the product of the highest number of FTE residents in any program year during the third year of the first new program, for each new residency training program established during that 3-year period, and the minimum accredited length for each type of program. This 3-year period, which we will refer to as the "3-year window" for ease of reference in this proposed rule, started when a new program began, and the teaching hospital first began to train residents for the first time in that new program, typically on July 1, and ending when the third program year of that first new program ends.

Prior to development of the FY 2013 IPPS/LTCH PPS proposed rule, the teaching hospital community expressed concerns that 3 years do not provide for a sufficient amount of time for a hospital to "grow" its new residency programs and to establish FTE resident caps that are properly reflective of the number of FTE residents that it will actually train, once the programs are fully grown. Hospitals explained that 3 years is an insufficient amount of time primarily because a period of 3 years is not compatible with program accreditation requirements, particularly in instances where the qualifying teaching hospital wishes to start more than one new program. Therefore, in the FY 2013 IPPS/LTCH PPS proposed rule and final rule, we proposed and finalized changes to the regulations at 42 CFR 413.79(e) for direct GME and at 42 CFR 412.105(f)(1)(vii) for IME that revised the "3-year window" to a "5-year window," for a new teaching hospital to establish and grow a new program, and thus begin training residents for the first time in new programs that are started on or after October 1, 2012. Thus, for urban hospitals that begin to train residents in a new medical residency training program for the first time on or after October 1, 2012, the cap will not be adjusted for new programs established more than 5 years after residents begin training in the first new program. However, rural hospitals are permitted to receive new cap adjustments for participating in training residents in new medical residency training programs at any time, and therefore, under § 413.79(e)(3), if a rural hospital participates in new medical residency training programs on or after October 1, 2012, the hospital's cap is adjusted for each new program based on a 5-year growth window. We refer readers to the FY 2013 IPPS/LTCH PPS final rule for more details on this change in the regulations regarding the 5-year window for urban hospitals training residents in new medical residency training programs for the first time and for rural hospitals participating in new medical residency training programs (77 FR 53416 through 53424).

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50111), we changed our policy regarding implementation of the FTE resident caps for new programs to be effective with the beginning of the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of the first new program started for hospitals for which the FTE cap may be adjusted in accordance with § 413.79(e)(1), and beginning with the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of each individual new program started for rural hospitals for which the FTE cap may be adjusted in accordance with § 413.79(e)(3). In the same final rule, we also made the effective dates of the 3-year rolling average and IME IRB ratio cap consistent with the effective date of the new program FTE resident caps. That is, beginning with the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of the first new program started for hospitals for which the FTE cap may be adjusted in accordance with § 413.79(e)(1), and beginning with the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of each individual new program started for rural hospitals for which the FTE cap may be adjusted in accordance with § 413.79(e)(3), FTE residents participating in new medical residency training programs are included in the hospital's IRB ratio cap and the 3-year rolling average.

b. Proposed Policy Changes Relating to Rural Training Tracks at Urban Hospitals

To encourage the training of residents in rural areas, section 407(c) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106–113) amended section 1886(h)(4)(H) of the Act to add a provision (subsection (iv)) that, in the case of a hospital that is not located in a rural area (an urban hospital) that establishes separately accredited approved medical residency training programs (or rural tracks) in a rural area or has an accredited training program with an integrated rural track, the Secretary shall adjust the urban hospital's cap on the number of FTE residents under subsection (F), in an appropriate manner in order to encourage training of physicians in rural areas. Section 407(c) of Public Law 106–113 was made effective for direct GME payments to hospitals for cost reporting periods beginning on or after April 1, 2000, and for IME payments applicable to discharges occurring on or after April 1, 2000. We refer readers to the August 1, 2000 interim final rule with comment period (65 FR 47033 through 47037) and the FY 2002 IPPS final rule (66 FR 39902 through 39909) where we implemented section 407(c) of Public Law 106–113. The regulations for establishing rural track FTE limitations are located at 42 CFR 413.79(k) for direct GME and at 42 CFR 412.105(f)(1)(x) for IME.

In the August 1, 2003 IPPS final rule (68 FR 45456 through 45457), we clarified our existing policy that although the rural track provision allows an increase to the urban hospital's FTE cap, sections 1886(h)(4)(H)(iv) and 1886(d)(5)(B) of the Act do not provide for an exclusion from the rolling average for the urban hospital for those FTE residents training in a rural track. These provisions are interpreted to mean that, except for new rural track programs begun by urban teaching hospitals that are establishing an FTE cap for the first time, when an urban hospital with an FTE resident cap establishes a new rural track program or expands an existing rural track program, FTE residents in the rural track that are counted by the urban hospital are included in the hospital's rolling average calculation immediately. This policy is reflected in the regulation at § 412.105(f)(1)(v)(F) for IME and § 413.79(d)(7) for direct GME, and applies for IME and direct GME to cost reporting periods beginning on or after April 1, 2000.

We received questions asking whether the change in the 3-year window to the 5-year window for new programs also applies to the establishment of rural training tracks. In the FY 2013 IPPS/LTCH PPS final rule, when we amended the regulations to provide for a 5-year new program growth window at § 413.79(e) for direct GME and at § 412.105(f)(1)(vii) for IME, and in the FY 2015 IPPS/LTCH PPS final rule when we made the FTE resident caps of new programs to be effective with the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year, we inadvertently did not also change the growth window and effective date of FTE limitations for rural training tracks, which, under existing § 413.79(k) for direct GME and § 412.105(f)(1)(x) for IME, is 3 program years, and is effective after 3 program years, respectively.

In this FY 2017 IPPS/LTCH PPS proposed rule, we are proposing to revise the regulations at § 413.79(k) (and which, in turn, would affect IME adjustments under § 412.105(f)(1)(x)) to permit that, in the first 5 program years (rather than the first 3 program years) of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents training in the rural training track at the urban hospital, and beginning with the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural training track's existence, the rural track FTE limitation would take effect. This proposed change addresses concerns expressed by the hospital community that rural training tracks, like any program, should have a sufficient amount of time for a hospital to "grow" and to establish a rural track FTE limitation that reflects the number of FTE residents that it will actually train, once the program is fully grown.

However, as stated above, due to the statutory language at sections 1886(d)(5)(B) and 1886(h)(4)(H)(iv) of the Act as implemented in our regulations at §§ 412.105(f)(1)(v)(F) and 413.79(d)(7), except for new rural track programs begun by urban teaching hospitals that are establishing an FTE cap for the first time, FTE residents in a rural track training program at the urban hospital are subject immediately to the 3-year rolling average for direct GME and IME. In addition, under the regulations at § 412.105(a)(1)(i), no exception to the IME intern- and resident-to-bed (IRB) ratio cap is provided for residents in a rural track training program (except for new rural track programs begun by urban teaching hospitals that are establishing an FTE cap for the first time). Accordingly, while we are proposing that the urban hospital's rural track FTE limitation would first be effective beginning with the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track training program's existence, the rural track training program's FTEs are included in the 3-year rolling average and are subject to the IME IRB ratio cap for hospitals with established FTE caps, even within the first 5 program years prior to the beginning of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track training program's existence.

We note that, for programs with cost reporting periods beginning on or after October 1, 2003, our regulations at §§ 413.79(k)(1) through (k)(4) are divided between rural track FTE limitation adjustments for urban hospitals where the residents rotate to a rural area for more than one half of the duration of the program (§§ 413.79(k)(1) and (k)(2)), and where the residents rotate to a rural area for less than one-half of the duration of the program (§§ 413.79(k)(3) and (k)(4)). As we explained in the August 1, 2003 IPPS final rule (68 FR 45456 through 45458), "duration of the program" refers to the minimum accredited length of the particular specialty of the rural track training program. We are clarifying under this proposal that, although the urban hospital's rural track FTE limitation would not be effective until the beginning of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track training program's existence, the rural track FTE limitation that would be provided, if any, is still subject to whether or not the urban hospital rotates the residents in the rural track training program to a rural area(s) for more than one-half of the "duration of the program," and whether or not the urban hospital complies with existing §§ 413.79(k)(5) and (k)(6), and the proposed revised § 413.79(k)(7). We are proposing to revise § 413.79(k)(7), which specifies the effect on rural track FTE limitations when previously rural statistical areas become urban statistical areas due to updates in the OMB standards for delineating urban and rural statistical areas, because the existing paragraphs under § 413.79(k)(7) discuss the "3-year" growth period. Consequently, we need to make conforming changes by revising paragraphs (k)(7)(ii) and (iii) to account for rural track training programs started prior to October 1, 2012. (For more information regarding the effect on rural track FTE limitations when OMB makes changes to its standards for delineating statistical areas, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50113 through 50117).)

c. Proposed Effective Date

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50111), when we provided that the policy regarding the effective dates of the FTE residency caps, the 3-year rolling average, and the IRB ratio cap for FTE residents in new medical residency training programs would be effective with the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of the first new program started, we stated that this policy would be effective for urban hospitals that first begin to participate in training residents in their first new medical residency training program, and for rural hospitals, on or after October 1, 2012. We finalized this as the effective date because the policy providing a 5-year growth period for establishing the FTE resident caps (§§ 413.79(e)(1) and (e)(3)) was also effective for new programs started on or after October 1, 2012. Because we inadvertently did not also amend the separate regulations at § 412.105(f)(1)(x) and § 413.79(k) regarding the growth window and effective date of FTE limitations for rural track training programs when we amended the regulations regarding the 5-year growth window in the FY 2013 IPPS/LTCH PPS final rule and regarding the additional changes we made in the FY 2015 IPPS/LTCH PPS final rule, we are proposing that the effective date regarding the change in the growth window for rural track training programs from 3 years to 5 years also be effective for rural track training programs started on or after October 1, 2012. We acknowledge that there could be urban hospitals that started a rural track training program after October 1, 2012 (likely on July 1, 2013) for which rural track FTE limitations would become effective under current policy after 3 years (likely on July 1, 2016). We are proposing that, if our proposal is finalized, we would not actually apply the rural track FTE limitations that would have become effective for these hospitals after 3 program years. Instead, the rural track FTE limitations for these hospitals would be the actual number of FTE residents training in the rural track (subject to the rolling average at § 413.79(d)(7) and the IME IRB ratio cap at § 412.105(a)(1)(i), if applicable) for an additional 2 years (from July 1, 2016 through June 30, 2018), and the rural track FTE limitations would become effective with the cost reporting period that coincides with or follows the start of the sixth program year, which in this example would be July 1, 2018.

In summary, we are proposing to revise the direct GME regulations at § 413.79(k) (and which, in turn, would affect IME adjustments under § 412.105(f)(1)(x)) to permit that, effective with rural track training programs started on or after October 1, 2012, in the first 5 program years of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents (subject to the rolling average at § 413.79(d)(7) and the IME IRB ratio cap at § 412.105(a)(1)(i), if applicable), training in the rural track training program at the urban hospital, and the rural track FTE limitation would take effect beginning with the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track training program's existence.

We are inviting public comment on this proposal.

K. Rural Community Hospital Demonstration Program

1. Background

Section 410A(a) of Public Law 108–173 required the Secretary to establish a demonstration program to test the feasibility and advisability of establishing "rural community" hospitals to furnish covered inpatient hospital services to Medicare beneficiaries. The demonstration pays rural community hospitals under a reasonable cost-based methodology for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. A rural community hospital, as defined in section 410A(f)(1), is a hospital that—

- Is located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act;
- Has fewer than 51 beds (excluding beds in a distinct part psychiatric or rehabilitation unit) as reported in its most recent cost report;
- Provides 24-hour emergency care services; and

- Is not designated or eligible for designation as a CAH under section 1820 of the Act.

Section 410A(a)(4) of Public Law 108–173 specified that the Secretary was to select for participation no more than 15 rural community hospitals in rural areas of States that the Secretary identified as having low population densities. Using 2002 data from the U.S Census Bureau, we identified the 10 States with the lowest population density in which rural community hospitals were to be located in order to participate in the demonstration: Alaska, Idaho, Montana, Nebraska, Nevada, New Mexico, North Dakota, South Dakota, Utah, and Wyoming. (Source: U.S. Census Bureau, Statistical Abstract of the United States: 2003.)

CMS originally solicited applicants for the demonstration in May 2004; 13 hospitals began participation with cost reporting periods beginning on or after October 1, 2004. In 2005, 4 of these 13 hospitals withdrew from the program and converted to CAH status. This left 9 hospitals participating at that time. In 2008, we announced a solicitation for up to 6 additional hospitals to participate in the demonstration program. Four additional hospitals were selected to participate under this solicitation. These 4 additional hospitals began under the demonstration payment methodology with the hospital's first cost reporting period starting on or after July 1, 2008. At that time, 13 hospitals were participating in the demonstration.

Five hospitals (3 of the hospitals were among the 13 hospitals that were original participants in the demonstration program and 2 of the hospitals were among the 4 hospitals that began the demonstration program in 2008) withdrew from the demonstration program during CYs 2009 and 2010. (Three of these hospitals indicated that they would be paid more for Medicare inpatient hospital services under the rebasing option allowed under the SCH methodology provided for under section 122 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275). One hospital restructured to become a CAH, and one hospital closed.) In CY 2011, one hospital that was among the original set of hospitals that participated in the demonstration withdrew from the demonstration. These actions left seven of the originally participating hospitals (that is, hospitals that were selected to participate in either 2004 or 2008) participating in the demonstration program as of June 1, 2011.

Sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148) amended section 410A of Public Law 108–173, changing the rural community hospital demonstration program in several ways. First, the Secretary is required to conduct the demonstration program for an additional 5-year period, to begin on the date immediately following the last day of the initial 5-year period. Further, the Affordable Care Act requires, in the case of a rural community hospital that is participating in the demonstration program as of the last day of the initial 5-year period, the Secretary to provide for the continued participation of such rural hospital in the demonstration program during the 5-year extension period, unless the hospital makes an election to discontinue participation.

In addition, the Affordable Care Act provides that, during the 5-year extension period, the Secretary shall expand the number of States with low population densities determined by the Secretary to 20. Further, the Secretary is required to use the same criteria and data that the Secretary used to determine the States for purposes of the initial 5-year period. The Affordable Care Act also allows not more than 30 rural community hospitals in such States to participate in the demonstration program during the 5-year extension period.

We published a solicitation for applications for additional participants in the rural community hospital demonstration program in the **Federal Register** on August 30, 2010 (75 FR 52960). Applications were due on October 14, 2010. The 20 States with the lowest population density that were eligible for the demonstration program are: Alaska, Arizona, Arkansas, Colorado, Idaho, Iowa, Kansas, Maine, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Utah, and Wyoming (Source: U.S. Census Bureau, Statistical Abstract of the United States: 2003). We approved 19 new hospitals for participation in the demonstration program. We determined that each of these new hospitals would begin participating in the demonstration with its first cost reporting period beginning on or after April 1, 2011.

Three of these 19 hospitals declined participation prior to the start of the cost reporting periods for which they would have begun the demonstration. In addition to the 7 hospitals that were selected in either 2004 or 2008, the new selection led to a total of 23 hospitals in the demonstration. During CY 2013, one additional hospital among the set selected in 2011 withdrew from the demonstration, similarly citing a relative financial advantage to returning to the customary SCH payment methodology, which left 22 hospitals participating in the demonstration, effective July 1, 2013. In October 2015, another hospital among those selected in 2011 closed, leaving 14 among this cohort still participating. (By this date, as described below, the 7 hospitals that were selected in either 2004 or 2008 had completed the 5-year extension period mandated by the Affordable Care Act).

Section 410A(c)(2) of Public Law 108–173 required that, in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented. This requirement is commonly referred to as "budget neutrality." Generally, when we implement a demonstration program on a budget neutral basis, the demonstration program is budget neutral in its own terms; in other words, the aggregate payments to the participating hospitals do not exceed the amount that would be paid to those same hospitals in the absence of the demonstration program. Typically, this form of budget neutrality is viable when, by changing payments or aligning incentives to improve overall efficiency, or both, a demonstration program may reduce the use of some services or eliminate the need for others, resulting in reduced expenditures for the demonstration program's participants. These reduced expenditures offset increased payments elsewhere under the demonstration program, thus ensuring that the demonstration program as a whole is budget neutral or yields savings. However, the small scale of this demonstration program, in conjunction with the payment methodology, makes it extremely unlikely that this demonstration program could be viable under the usual form of budget neutrality.

Specifically, cost-based payments to participating small rural hospitals are likely to increase Medicare outlays without producing any offsetting reduction in Medicare expenditures elsewhere. Therefore, a rural community hospital's participation in this demonstration program is unlikely to yield benefits to the participant if budget neutrality were to be implemented by reducing other payments for these same hospitals. In the past 12 IPPS final rules, spanning the period for which the demonstration program has been implemented, we have adjusted the national inpatient PPS rates by an amount sufficient to account for the added costs of this demonstration program, thus applying budget neutrality across the payment system as a whole rather than merely across the participants in the demonstration program. As we discussed in the FYs 2005 through 2016 IPPS final rules (69 FR 49183; 70 FR 47462; 71 FR 48100; 72 FR 47392; 73 FR 48670; 74 FR 43922, 75 FR 50343, 76 FR 51698, 77 FR 53449, 78 FR 50740, 77 FR 50145, and 80 FR 49585, respectively), we believe that the language of the statutory budget neutrality requirements permits the agency to implement the budget neutrality provision in this manner.

2. Budget Neutrality Offset Adjustments: Fiscal Years 2005 Through 2016

a. Fiscal Years 2005 Through 2013

In general terms, in each of these previous years from FYs 2005 through 2016, we used available cost reports for the participating hospitals to derive an estimate of the additional costs attributable for the demonstration. For FYs 2005 through 2012, we used finalized, or settled, cost reports, as available, and "as submitted" cost reports for hospitals for which finalized cost reports were not available to derive this estimate of the additional costs attributable to the demonstration. Annual market basket percentage increase amounts provided by the CMS Office of the Actuary reflecting the growth in the prices of inputs for inpatient hospitals were applied to cost amounts obtained from these cost reports. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53452), we initiated two general changes to the methodology for estimating the costs of the demonstration (which we have continued to apply through FY 2016). First, we used "as submitted" cost reports for each hospital participating in the demonstration in estimating the costs of the demonstration (for FY 2013, we used cost reports for cost reporting periods ending in CY 2010). Second, in FY 2013, we incorporated different update factors (the market basket percentage increase and the applicable percentage increase, as applicable, to several years of data as opposed to solely using the market basket percentage increase) for the calculation of the budget neutrality offset amount. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53449 through 53453) for a detailed discussion of the methodology initiated in FY 2013.

In each of these fiscal years, an annual update factor provided by the CMS Office of the Actuary reflecting growth in the volume of inpatient operating services was also applied to update the estimated costs. For the budget neutrality calculations in the IPPS final rules for FYs 2005 through 2011, the annual volume adjustment applied was 2 percent; for the IPPS final rules for FYs 2012 through 2016, it was 3 percent. For a detailed discussion of our budget neutrality offset calculations, we refer readers to the IPPS final rule applicable to the fiscal year involved.

In general, for FYs 2005 through 2013, we based the budget neutrality offset estimate on the estimated cost of the demonstration in an earlier given year. For these periods, we derived that estimated cost by subtracting the estimated amount that would otherwise be paid without the demonstration in an earlier given year from the estimated amount for the same year that would be paid under the demonstration under the reasonable cost-based methodology authorized by section 410A of Public Law 108–173. (We ascertained the estimated amount that would be paid in an earlier given year under the reasonable cost methodology and the estimated amount that would otherwise be paid without the demonstration in an earlier given year from finalized or "as submitted" cost reports as discussed earlier.) For FYs 2005 through 2012, we then updated the estimated costs described earlier to the upcoming year by multiplying them by the market basket percentage increases applicable to the years involved and the applicable annual volume adjustment. Beginning in FY 2013, as discussed earlier, we began incorporating different update factors—we used the IPPS market basket percentage increases applicable to the years involved to update the estimated amount that would be paid under the demonstration under the reasonable cost-based methodology, and the applicable percentage increases applicable to the years involved to update the amounts that would otherwise be paid without the demonstration. We continued to apply the annual volume adjustment as discussed earlier.

For the FY 2010 IPPS/RY 2010 LTCH PPS final rule, data from finalized cost reports reflecting the participating hospitals' experience under the demonstration were available. Specifically, the finalized cost reports for the first 2 years of the demonstration, that is, cost reports for cost reporting years beginning in FYs 2005 and 2006 (CYs 2004, 2005, and 2006) were available. These data showed that the actual costs of the demonstration for these years exceeded the amounts originally estimated in the respective final rules for the budget neutrality adjustment. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule, we included an additional amount in the budget neutrality offset amount in that fiscal year. This additional amount was based on the amount that the costs of the demonstration for FYs 2005 and 2006 exceeded the budget neutrality offset amounts finalized in the IPPS rules applicable for those years.

In the final rules for FYs 2011 through 2013, we continued to use a methodology for calculating the budget neutrality offset amount consisting of two components: (1) The estimated demonstration costs in the upcoming fiscal year; and (2) the amount by which the actual demonstration costs corresponding to an earlier, given year (which would be known once finalized cost reports became available for that year) exceeded the budget neutrality offset amount finalized in the corresponding year's IPPS final rule. However, we noted in the FYs 2011, 2012, and 2013 IPPS final rules that, because of a delay affecting the settlement process for cost reports for IPPS hospitals occurring on a larger scale than merely for the demonstration, we were unable to finalize this component of the budget neutrality offset amount accounting for the amount by which the actual demonstration costs in an earlier given year exceeded the budget neutrality offset amount finalized in the corresponding year's IPPS final rule for cost reports of demonstration hospitals dating to those beginning in FY 2007.

b. Fiscal Years 2014 and 2015

In the final rules for FYs 2014 and 2015, we continued to apply the general methodology discussed earlier (with the modifications initiated in FY 2013) in estimating the costs of the demonstration for the specific fiscal year, using the set of "as submitted" cost reports from the most recent calendar year for which they are available (cost reporting periods ending in 2011 and 2012, respectively), and updating the cost amounts according to the factors discussed earlier. In addition, in these final rules, because finalized cost reports for FYs 2007 and 2008 had become available, we were able to include in the budget neutrality offset adjustment the amount by which the actual demonstration costs in each of those years exceeded the budget neutrality offset amounts finalized in the IPPS final rules for these years.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR through 50744), we determined the final budget neutrality offset amount to be applied to the FY 2014 IPPS rates to be $52,589,741. This amount was comprised of the two distinct components identified earlier: (1) The final resulting difference between the total estimated FY 2014 reasonable cost amount to be paid under the demonstration to the 22 participating hospitals for covered inpatient hospital services, and the total estimated amount that would otherwise be paid to such hospitals without the demonstration (this amount was $46,549, 861); and (2) the amount by which the actual costs for the demonstration for FY 2007 (as shown in the finalized cost reports for cost reporting periods beginning in FY 2007 for the nine hospitals that participated in the demonstration during FY 2007) exceeded the budget neutrality offset amount that was finalized in the FY 2007 IPPS final rule (this amount was $6,039,880).

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50141 through 50145), we determined the final budget neutrality offset amount to be applied to the FY 2015 IPPS rates to be $64,566,915. This amount was also comprised of the two earlier referenced components: (1) The final resulting difference between the total estimated FY 2015 reasonable cost amount to be paid under the demonstration to the 22 participating hospitals for covered inpatient hospital services, and the total estimated amount that would otherwise be paid to such hospitals in FY 2015 without the demonstration (this amount was $54,177,144); and (2) the amount by which the actual costs of the demonstration for FY 2008 (as shown in the finalized cost reports for the hospitals that participated in the demonstration during FY 2008) exceeded the budget neutrality offset amount that was finalized in the FY 2008 IPPS final rule (this amount was $10,389,771).

c. Fiscal Year 2016

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49586 through 49591), we continued to apply the general methodology discussed earlier for FYs 2014 and 2015 in estimating the costs of the demonstration for FY 2016, with some modifications. For FY 2016, we used the set of "as submitted" cost reports from the most recent calendar year for which they were available (cost reporting periods ending in CY 2013), and updated the cost amounts using the IPPS market basket percentage increase and applicable percentage increase applicable to the years involved as discussed earlier. Although the methodology for FY 2016 was similar to that for the previous several rules, because the demonstration began to phase out prior to the beginning of FY 2016, appropriate changes to the calculations were made. The 7 "originally participating hospitals," that is, those hospitals that were selected for the demonstration in either 2005 or 2008, were scheduled to end their participation in the 5-year extension period authorized by the Affordable Care Act prior to the start of FY 2016. Therefore, we did not include the financial experience of these hospitals in the calculation of either the estimated reasonable cost amount or the estimated amount that otherwise would be paid without the demonstration for FY 2016. In addition, 8 hospitals that entered the demonstration in 2011 and 2012 through the solicitation that followed the Affordable Care Act amendments expanding the demonstration, and that were still participating in the demonstration at the time of the FY 2016 IPPS/LTCH PPS final rule, were scheduled to end their participation on a rolling basis before September 30, 2016. As discussed in the FY 2016 IPPS/LTCH PPS final rule, for these 8 hospitals, the estimated reasonable cost amount and the estimated amount that would otherwise be paid without the demonstration were prorated according to the ratio of the number of months between October 1, 2015, and the end of the hospital's cost reporting period in relation to the entire 12-month period. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49586 through 49588) for a discussion of these additional calculations.

The resulting estimate of costs of the demonstration for FY 2016 for the 15 hospitals participating in the demonstration for FY 2016 was $26,044,620.

In addition, in the FY 2016 IPPS/LTCH PPS final rule, we were able to finalize the amounts by which the actual demonstration costs for FYs 2009 and 2010 differed from the budget neutrality offset amount finalized in the corresponding final rules for these years using the following approach:

We identified the difference between the actual cost of the demonstration for FY 2009 as indicated in the finalized cost reports for hospitals that participated in FY 2009 and that had cost reporting periods beginning in FY 2009 (this amount was $14,332,936), and the budget neutrality offset amount that was identified in the FY 2009 IPPS final rule (73 FR 48671) (this amount was $22,790,388). Analysis of this set of cost reports showed that the budget neutrality offset amount that was finalized to account for the demonstration costs in FY 2009 (as set forth in the FY 2009 IPPS final rule) exceeded the actual cost of the demonstration for FY 2009 by $8,457,452.

We included the amount by which the actual costs of the demonstration for FY 2010 (as shown in the finalized cost reports for the nine hospitals that completed a cost reporting period beginning in FY 2010) ($16,817,922) differed from the amount that was finalized as the costs of the demonstration for FY 2010 as set forth in the FY 2010 IPPS/RY 2010 LTCH PPS final rule and the FY 2011 IPPS/LTCH PPS final rule ($21,569,472). Analysis of this set of cost reports showed that the budget neutrality offset amount that was finalized to account for the demonstration costs in FY 2010 (as set forth in the FY 2010 IPPS/RY 2010 LTCH PPS final rule and the FY 2011 IPPS/LTCH PPS final rule) exceeded the actual cost of the demonstration for FY 2010 by $4,751,550.

Unlike in previous years, because the budget neutrality offset amount identified in the corresponding final rules for each of FYs 2009 and 2010 exceeded the actual costs of the demonstration, we subtracted the differences between these amounts for each fiscal year (that is, $8,457,452 applicable to FY 2009 and $4,751,550 applicable to FY 2010) from the estimated amount of the costs of the demonstration for FY 2016 (that is, $26,044,620). Thus, the final budget neutrality offset amount for which the adjustment to the national IPPS rates was calculated was $12,835,618.

3. Proposed Budget Neutrality Methodology for FY 2017

As described earlier, we have generally incorporated two components into the budget neutrality offset amounts identified in the final IPPS rules in previous years. First, we have estimated the costs of the demonstration for the upcoming fiscal year, generally determined from historical, "as submitted" cost reports for the hospitals participating in that year. Update factors representing nationwide trends in cost and volume increases have been incorporated into these estimates, as specified in the methodology described in the final rule for each fiscal year. Second, as finalized cost reports have become available, we have determined the amount by which the actual costs of the demonstration for an earlier, given year differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year, and we incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. If the actual costs for the demonstration for the earlier fiscal year exceeded the estimated costs of the demonstration identified in the final rule for that year, this difference was added to the estimated costs of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. Conversely, if the estimated costs of the demonstration set forth in the final rule for a prior fiscal year exceeded the actual costs of the demonstration for that year, this difference was subtracted from the estimated cost of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. We note that we have calculated this difference between the actual costs of the demonstration for FYs 2005 through 2010, as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

In this FY 2017 proposed rule, we are proposing a different methodology as compared to previous years for analyzing the costs attributable to the demonstration for FY 2017. We note that the demonstration will have substantially phased out by the beginning of FY 2017. The 7 "originally participating hospitals," that is, those that were selected for the demonstration in 2004 and 2008, ended their participation in the 5-year extension period authorized by the Affordable Care Act prior to the start of FY 2016. In addition, the participation period for the 14 hospitals that entered the demonstration following upon the mandate of the Affordable Care Act and that are still participating will end on a rolling basis according to the end dates of the hospitals' cost report periods, respectively, from April 30, 2016 through December 31, 2016. (As noted earlier, 1 hospital among this cohort closed in October 2015). Of these 14 hospitals, 10 will end participation on or before September 30, 2016, leaving 4 hospitals participating for the last 3 months of CY 2016 (that is, the first 3 months of FY 2017). We believe that, given the small number of participating hospitals and the limited time of participation for such hospitals during FY 2017, a revised methodology is appropriate for determining the costs of the demonstration during this period as discussed below.

We note that estimating the costs of the demonstration for these 4 hospitals for their extent of participation in the demonstration in FY 2017 would entail a prorating calculation if we followed the methodology we used for FY 2016 as described earlier, as well as application of update factors to project increases in cost. We further note that, for the 4 hospitals that will end their participation in the demonstration effective December 31, 2016, the financial experience of the last 3 months of the calendar year (that is, the first 3 months of FY 2017) will be included in the finalized cost reports for FY 2016. (Consistent with the methodology used for the final rules for previous years, a hospital's cost report is included in the analysis of a given fiscal year if the cost reporting period begins in that fiscal year). We believe that examining the finalized cost reports for FY 2016 for these hospitals would lead to a more accurate and administratively feasible calculation of budget neutrality for the demonstration in FY 2017 than conducting an estimate of the costs of the demonstration for this 3-month period based on "as submitted cost reports" (as would occur according to the budget neutrality methodology currently in effect).

In addition, given that the extent of covered services for FY 2017 subject to the payment methodology under the demonstration is a small fraction of that in previous fiscal years, we believe that it is appropriate to forego the process of estimating the costs attributable to the demonstration for 2017 and to instead analyze the set of finalized cost reports for cost reporting periods beginning in FY 2016, which will reflect the actual cost of the demonstration, when they become available. Such an approach also would eliminate the need to perform for FY 2017 the second component of the budget neutrality methodology discussed earlier (that is, determining the amount by which the actual costs of the demonstration for the fiscal year, as determined in finalized cost reports once available, differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year). Thus, for the reasons discussed earlier, we are proposing to calculate the costs of the demonstration and the resulting budget neutrality adjustment factor for the demonstration for FY 2017 once the finalized cost reports for cost reporting periods beginning in FY 2016 become available. We are inviting public comments on this proposal.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49591), we stated that we intended to discuss in this FY 2017 IPPS/LTCH PPS proposed rule how we would reconcile the budget neutrality offset amounts identified in the IPPS final rules for FYs 2011 through 2016 with the actual costs of the demonstration for those years, considering the fact that the demonstration will end December 31, 2016. We believe it would be appropriate to conduct this analysis for FYs 2011 through 2016 at one time, when all of the finalized cost reports for cost reporting periods beginning in FYs 2011 through 2016 are available. Such an aggregate analysis encompassing the cost experience through the end of the period of performance of the demonstration represents an administratively streamlined method, allowing for the determination of any appropriate adjustment to the IPPS rates and obviating the need for multiple fiscal-year-specific calculations and regulatory actions. Given the general lag of 3 years in finalizing cost reports, we expect any such analysis to be conducted in FY 2020.

We also note that, in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49591), we indicated that we were considering whether to propose in future rulemaking that the calculation of the final costs of the demonstration for a fiscal year reflect that some of the participating hospitals would otherwise have been eligible for the payment adjustment for low-volume hospitals in that fiscal year if they had not participated in the demonstration. Our policy under the demonstration is that hospitals participating in the demonstration are not able to receive the low-volume adjustment in addition to the reasonable cost-based payment authorized by section 410A of Public Law 108–173. We refer readers to Change Request 7505 dated July 22, 2011, available on the CMS Web site at: *http://www.cms.gov.* Section 1886(d)(12) of the Act provides for a payment adjustment to account for the higher costs per discharge for low-volume hospitals under the IPPS, effective FY 2005 (69 FR 49099 through 49102). We note that sections 3125 and 10314 of the Affordable Care Act provided for temporary changes in the qualifying criteria and payment adjustment for low-volume hospitals for FYs 2011 and 2012, which have been extended through subsequent legislation: Through FY 2013, by the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240) (78 FR 50610 through 50613), through March 31, 2014, by the Pathway for SGR Reform Act (Pub. L. 113–67) (79 FR 15022 through 15025); through March 21, 2015, by the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93) (79 FR 49998 through 50001); and most recently through September 30, 2017, by section 204 of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub.

L. 114–110). These temporary changes have increased the number of hospitals that are eligible to receive the low-volume hospital payment adjustment.

We further stated in the FY 2016 IPPS/LTCH PPS final rule that taking the low-volume hospital payment adjustment into account in determining the costs of the demonstration would require detailed consideration of the data sources and methodology that would be used to determine which among the demonstration hospitals would have otherwise been eligible for the low-volume payment adjustment and to estimate the amount of the adjustment. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 24521), we invited public comments on this issue.

We are continuing to examine this issue and are considering whether to incorporate the low-volume payment adjustment amounts that would have otherwise been made into the calculation of the difference between the actual costs of the demonstration and budget neutrality offset amounts for FYs 2011 through 2016. We note that applying such a methodology may lower the calculated amounts of the actual costs of the demonstration compared to not applying such a methodology, making it more likely that the actual costs of the demonstration for a year will not exceed the estimated costs of the demonstration identified in the final rule for that year. We again are inviting public comments on this issue.

L. Proposed Hospital and CAH Notification Procedures for Outpatients Receiving Observation Services

1. Background

a. Statutory Authority

On August 6, 2015, the Notice of Observation Treatment and Implication for Care Eligibility Act (the NOTICE Act), Public Law 114–42 was enacted. Section 2 of the NOTICE Act amended section 1866(a)(1) of the Act by adding new subparagraph (Y) that requires hospitals and critical access hospitals (CAHs) to provide written notification and an oral explanation of such notification to individuals receiving observation services as outpatients for more than 24 hours at the hospitals or CAHs. Section 1866(a)(1) of the Act lists requirements for providers of services to participate in the Medicare program and be eligible for payments under Medicare pursuant to provider agreements.

Section 1866(a)(1)(Y) of the Act, as added by section 2 of the NOTICE Act, specifies that the notification process must consist of a written notification as specified by the Secretary through rulemaking and containing such language as the Secretary prescribes consistent with the statutory provision, and an oral explanation of the written notification and documentation of the provision of the explanation, as the Secretary determines to be appropriate. Notification to each individual who receives observation services as an outpatient for more than 24 hours must be provided no later than 36 hours after observation services are initiated (or sooner, if upon release from the hospital or CAH). Section 1866(a)(1)(Y)(ii) of the Act provides that the written notice must explain that the individual is an outpatient receiving observation services, and is not an inpatient of a hospital or CAH. In addition, the written notice must include the reason(s) the individual is an outpatient receiving observation services and must explain the implications of being an outpatient receiving observation services, such as cost-sharing requirements and post-hospitalization eligibility for coverage of skilled nursing facility (SNF) services under Medicare. The written notification also must include any additional information as deemed appropriate by the Secretary. Moreover, the written notification must either be signed by the individual receiving observation services as an outpatient, or a person acting on the individual's behalf, to acknowledge receipt of the notification. In cases where a signature by the individual or the person acting on the individual's behalf is refused, section 1866(a)(1)(Y)(ii)(IV)(bb) of the Act stipulates that the notification be signed by the staff member of the hospital or CAH who presented the written notification and include the name and title of the staff member, a certification statement that the notification was presented, and the date and time that the notification was presented. Finally, section 1866(a)(1)(Y)(ii)(V) of the Act provides that the notification be written and formatted using plain language and is made available in appropriate languages as determined by the Secretary.

b. Proposed Effective Date

Section 2 of the NOTICE ACT provides the effective date for this notification requirement as effective beginning 12 months after the date of enactment of the NOTICE Act; that is, effective on August 6, 2016. Since the date the NOTICE Act was enacted, CMS has been working to implement the statutory requirement in a timely manner. On December 14, 2015, CMS released an electronic mailbox address for individuals who wished to submit email comments on the provisions of the NOTICE Act. In addition, CMS announced a December 21, 2015 listening session to provide individuals further opportunity to provide comment on the NOTICE Act. We thank those individuals who shared their input. The agency reviewed all comments submitted by email as well as those comments provided during the public listening session in developing the provisions of this proposed rule.

2. Proposed Implementation of the NOTICE Act Provisions

a. Proposed Notice Process

In this proposed rule, we are proposing to implement section 1866(a)(1)(Y) of the Act by revising the requirements that providers agree to as part of participating in Medicare under a provider agreement by establishing regulations (at proposed 42 CFR 489.20(y)) that would specify a process for hospitals and CAHs to notify an individual, orally and in writing, regarding the individual's receipt of observation services as an outpatient and the implications of receiving such services as set forth below. Under this proposed process, hospitals and CAHs would be required to furnish notice to such an individual entitled to Medicare benefits if the individual receives observation services as an outpatient for more than 24 hours. We are proposing the use of a standardized notice, referred to as the Medicare Outpatient Observation Notice (MOON), to be used by all applicable hospitals and CAHs. The MOON would include all of the informational elements required by section 1866(a)(1)(Y)(ii) of the Act to fulfill the written notice requirement of the NOTICE Act.

b. Proposed Notification Recipients

Section 1866(a)(1)(Y) of the Act requires hospitals or CAHs to furnish notice to each individual who receives observation services as an outpatient at such hospital or CAH for more than 24 hours. Throughout section 1866 of the Act, "individual" generally refers to a person entitled to have payment made for services under Title XVIII of the Act, or a person not entitled to have payment made for services under Title XVIII if certain conditions are met. The provisions of the NOTICE Act specify that notice must be provided to individuals receiving observation services as an outpatient for more than 24 hours; the provisions do not specify qualifications related to payment for such services as a condition of notice. Accordingly, we are proposing under the new § 489.20(y) that the notification required by section 1866(a)(1)(Y) of the

Act must be provided to individuals entitled to benefits under Title XVIII of the Act, whether or not the services furnished are payable under Title XVIII, when individuals receive observation services as an outpatient for more than 24 hours. For example, an individual receiving Medicare Part A benefits who has not enrolled in Part B would still receive notice even though the observation services the individual receives as an outpatient would not be covered under Medicare for him or her, as such observation services received as an outpatient would fall under the Part B benefit and would be subject to payment under Medicare Part B.

A beneficiary enrolled in a Medicare Advantage or other Medicare health plan would receive the required notice under the existing rules that apply to hospitals and CAHs under a provider agreement governed by the provisions of section 1866(a)(1)(Y) of the Act. The Medicare Advantage regulations related to selection and credentialing of contract providers at 42 CFR 422.204(b)(3) require that, with respect to providers that meet the definition of "provider of services" as defined in section 1861(u) of the Act, basic benefits may only be provided by these providers if they have a provider agreement with CMS permitting them to provide services under original Medicare. Under section 1861(u) of the Act, the term "provider of services" means a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, or, for purposes of section 1814(g) and section 1835(e) of the Act, a fund.

Observation services are always provided under a physician's order that specifies the initiation of observation services. As a general matter, hospital observation services are defined in the Medicare Benefits Policy Manual (Pub. 100–02), Chapter 6, Section 20.6, as services that are medically reasonable and necessary, specifically ordered by a physician or other nonphysician practitioner authorized by State licensure law and hospital staff bylaws to admit patients to the hospital or to order outpatient services, and meet other published Medicare criteria for payment. The term "physician" will encompass these authorized qualified nonphysician practitioners for the purposes of this proposed rule. Individuals receiving observation services will always be registered as outpatients; however, not all outpatients receive observation services. "Outpatient," as defined in the Medicare Claims Processing Manual (Pub. 100–04), Chapter 1, Section 50.3.1, means "a person who has not been admitted as an inpatient but who is registered on the hospital or critical access hospital (CAH) records as an outpatient and receives services (rather than supplies alone) directly from the hospital or CAH." We are proposing that the provisions in this proposed rule would apply to the subset of individuals entitled to benefits under Title XVIII of the Act who are receiving treatment as outpatients and are receiving observation services for more than 24 hours. For outpatients who are not receiving observation services, or who are receiving observation services but not for more than 24 hours, hospitals and CAHs would not be required to deliver notice.

c. Proposed Timing of Notice Delivery

As provided at section 1866(a)(1)(Y) of the Act, we are proposing under proposed new § 489.20(y) that hospitals and CAHs must provide notice to an individual who receives observation services as an outpatient for more than 24 hours and that such notice must be furnished no later than 36 hours after observation services are initiated, or sooner if the individual is transferred, discharged, or admitted as an inpatient.

For purposes of this proposed rule, consistent with existing billing rules, observation services are initiated when a physician orders such services. According to the Medicare Claims Processing Manual (Pub. 100–04), Chapter 4, Section 290.2.2, hospital reporting for observation services "begins at the clock time documented in the patient's medical record, which coincides with the time that observation services are initiated in accordance with a physician's order." Because valid medical documentation for observation services will always contain the time when observation services are initiated, we believe hospitals and CAHs will be able to readily determine the timeframe within which the notice must be delivered. We expect that there will be cases where an individual receives more than 24 hours of observation services and has not yet received the MOON, but there are imminent plans for discharge to home or another facility, transfer to another unit or facility to receive care that does not include observation services, or admission to the hospital or another facility as an inpatient. In these cases, pursuant to section 1866(a)(1)(Y) of the Act, which provides that notice be provided not later than 36 hours after the time such an individual begins receiving such services (or, if sooner, upon release), we are proposing that the MOON must be given sooner than the 36-hour time limit for delivery because the MOON must be delivered before the individual is discharged, transferred, or admitted. When there are no plans to transfer, discharge, or admit an individual who receives observation services for more than 24 hours, we are proposing that the MOON must be provided within 36 hours of the initiation of observation services.

In rare circumstances where a physician initially orders inpatient services, but following internal utilization review (UR) performed while the patient is hospitalized, the hospital determines that the services do not meet its inpatient criteria and the physician concurs with UR, orders the discontinuation of inpatient services and initiation of outpatient observation services (that is, a Condition Code 44 situation), the MOON would be delivered as required by the NOTICE Act (when outpatient observation services have been ordered and furnished for more than 24 hours). If observation services are ordered when Condition Code 44 applies, the 24-hour time period for observation notification commences at the same time that observation services are initiated under a physician's order, consistent with existing policy for observation services furnished to outpatients. (We refer readers to the Medicare Claims Processing Manual, (Pub. 100–04), Chapter 1, Section 50.3.)

As stated in the notice announcing CMS Ruling CMS–1455–R (78 FR 16614), the Part B Inpatient Billing Ruling, in cases where CMS reviewers find that an inpatient admission was not medically reasonable and necessary after the beneficiary is discharged, and thus, not appropriate for payment under Medicare Part A, the beneficiary's patient status remains "inpatient" as of the time of the inpatient admission. The patient's status is not changed to outpatient because the beneficiary was formally admitted as an inpatient, and there is no provision to change a beneficiary's status after he or she is discharged from the hospital. Where CMS denies a claim after the beneficiary has been discharged because the inpatient admission was not medically reasonable and necessary, there would be no need to issue the MOON because the individual's status remains inpatient, despite the fact that the inpatient admission was improper. Similarly, where a hospital determines through UR after a beneficiary is discharged that his or her inpatient admission was not reasonable and necessary and the hospital bills the services that were provided on a Medicare Part B claim, the NOTICE Act notification requirements would not apply for these individuals because their status would also remain inpatient.

d. Proposed Requirements for Written Notice

We are proposing to implement section 1866(a)(1)(Y)(ii) of the Act, the requirement for written notification, under proposed new § 489.20(y)(1) by proposing the basic requirements for the written notice that hospitals and CAHs must use to notify individuals receiving outpatient observation services. Specifically, we are proposing that hospitals and CAHs would be required to use a proposed standardized notice (the MOON) for written notification to an individual who receives observation services as an outpatient under the appropriate circumstances. By requiring use of a standardized notice, hospitals and CAHs would be assured that they are providing all of the statutorily required elements in a manner that is understandable to individuals receiving the notice. As provided at section 1866(a)(1)(Y)(ii)(I) of the Act, we are proposing at § 489.20(y)(1)(i) that the proposed MOON would explain to individuals that they are outpatients receiving observation services and not inpatients of the hospital or CAH, and the reason(s) for such status as an outpatient receiving observation services. By definition (as specified in the Medicare Benefits Policy Manual, (Pub. 100–02), Chapter 6, Section 20.6), the reason for ordering observation services will always be the result of a physician's decision that the individual does not currently require inpatient services and observation services are needed for the physician to make a decision regarding whether the individual needs further treatment as a hospital inpatient or if the individual is able to be discharged from the hospital. We are proposing at § 489.20(y)(1)(ii) that the proposed MOON also would provide an explanation of the implications of receiving observation services furnished by a hospital or CAH as an outpatient, including services furnished on an inpatient basis, such as those related to cost-sharing requirements for the patient under Medicare, and post-hospitalization eligibility for Medicare-covered SNF care, in standardized language to ensure that all Medicare eligible individuals receive accurate information. We are proposing the inclusion of a blank "Additional Information" section on the MOON so that hospitals and CAHs may include additional information. Finally, as required by section 1866(a)(1)(Y)(ii)(V) of the Act, the proposed MOON would include this information in plain language written for beneficiary comprehension.

e. Outpatient Observation Services and Beneficiary Financial Liability

Section 20.6, Chapter 6, of the Medicare Benefit Policy Manual (Pub. 100–2) specifies that observation services furnished by hospitals and CAHs are "a well-defined set of specific, clinically appropriate services, which include ongoing short-term treatment, assessment, and reassessment before a decision can be made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital." Typically, observation services are ordered for individuals who present to the emergency department (ED) and who then require a significant period of treatment and monitoring to determine whether or not their condition warrants inpatient admission or discharge. Individuals also may receive outpatient observation services in other areas of a hospital or CAH when necessary. For example, a patient who receives a drug infusion in a hospital's outpatient infusion center and then experiences post-infusion hypertension may require observation services. In the majority of cases, the decision whether to discharge a patient from the hospital following resolution of the reason for the observation care or to admit the patient as an inpatient can be made in less than 48 hours, usually in less than 24 hours. In only rare and exceptional cases do reasonable and necessary outpatient observation services span more than 48 hours. All hospital observation services, regardless of duration of care, that are medically reasonable and necessary are covered by Medicare.

In some cases, Medicare beneficiaries receiving observation services while in a hospital or CAH may not be aware of their status as an inpatient or an outpatient, and thus may not be aware that there are significant differences in financial liability between inpatient status and outpatient status. CMS has published educational materials for Medicare beneficiaries to help inform them of financial and coverage liabilities associated with inpatient and outpatient services.[70] As an outpatient receiving observation services, a beneficiary may incur financial liability for Medicare Part B copayments,[71] the cost of self-administered drugs that are not covered under Part B, and the cost of post-hospital SNF care because section 1861(i) of the Act requires a prior 3-day hospital inpatient consecutive stay to be eligible for coverage of post-hospital SNF care under Medicare Part A. In contrast, as a hospital inpatient under Medicare Part A, a beneficiary pays an annual deductible ($1,288 in CY 2016) for all inpatient services provided during the first 60 days in the hospital of each benefit period for the year. Cost-sharing requirements for individuals enrolled in Medicare Part C, known as Medicare Advantage, health plans are dependent on the particular plan's policies. In addition, Medicare beneficiaries qualified through their State Medicaid program (QMBs) have different cost-sharing rules. For example, QMBs cannot be billed for Medicare Part A or Part B deductibles, coinsurance, and copayments and may have different rules regarding qualifying for SNF services. CMS has produced informational publications for beneficiaries that advise Medicare Advantage enrollees to check with their plans for information on coverage of observation services furnished to an outpatient.

As mentioned earlier, a beneficiary's liability for medication costs also is likely affected by whether the individual is hospitalized as an inpatient or receiving care as an outpatient. When an individual is hospitalized under a covered Medicare Part A inpatient stay, payment for medically reasonable and necessary medications that are provided by the hospital are covered under Medicare Part A. Generally, Medicare Part B covers drugs that are usually not self-administered. Based on the statutory prohibition at section 1861(s)(2) of the Act and its implementing regulation at 42 CFR 410.29(a), Medicare Part B generally does not cover or pay for any drug or biological that can be self-administered. "Self-administered drugs" are considered prescription and over-the-counter medications that beneficiaries routinely take on their own. For safety reasons, many hospitals do not allow patients to take medications brought from home.

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[70] "Are You a Hospital Inpatient or Outpatient? If You Have Medicare—Ask!" CMS Product No. 11435. May 2014.

[71] A beneficiary who receives hospital outpatient services typically pays 20 percent of the Medicare payment amount for outpatient items and services after paying the annual Part B deductible ($166 in CY 2016). The coinsurance amount for an outpatient CAH service is based on 20 percent of charges. In most cases, the cost-sharing for each individual outpatient service should not be more than the inpatient deductible. However, Medicare beneficiaries who receive several outpatient services, or are treated for extended periods of time as hospital outpatients, may have greater cost-sharing liabilities as an outpatient under observation than they may have if they were admitted as an inpatient to the hospital.

Medicare prescription drug plans (Part D) may help pay for drugs provided by the hospital. Individuals with Medicare Part D will likely need to pay out-of-pocket costs to the hospital for these drugs and request reimbursement from their Part D plan.

In addition, whether an individual is receiving treatment or care as an inpatient admitted to the hospital or is receiving observation services as an outpatient pursuant to a doctor's orders may impact Medicare coverage for post-hospital SNF services. Section 1861(i) of the Act requires a beneficiary to be an inpatient of a hospital for not less than 3 consecutive days before discharge from the hospital in order to be eligible for coverage of post-hospital extended care services in a SNF under Medicare. For purposes of Medicare SNF coverage, the time spent receiving observation services as an outpatient does not count towards the requirement of a 3-day hospital inpatient stay because these services are outpatient.

f. Delivering the Medicare Outpatient Observation Notice

An English language version of the proposed MOON was submitted to OMB for approval. Once we receive OMB approval, a Spanish language version of the MOON will be made available. If the individual receiving the notice is unable to read its written contents and/or comprehend the required oral explanation, we expect hospitals and CAHs to employ their usual procedures to ensure notice comprehension. (We refer readers, for example, to the Medicare Claims Processing Manual (Pub. 100–4), Chapter 30, Section 40.3.4.3., for similar existing procedures related to notice comprehension for the Advance Beneficiary Notice of Noncoverage (ABN).) Usual procedures may include, but are not limited to, the use of translators, interpreters, and assistive technologies. Hospitals and CAHs are reminded that recipients of Federal financial assistance have an independent obligation to provide language assistance services to individuals with limited English proficiency (LEP) consistent with section 1557 of the Affordable Care Act and Title VI of the Civil Rights Act of 1964. In addition, recipients of Federal financial assistance have an independent obligation to provide auxiliary aids and services to individuals with disabilities free of charge, subject to section 1557 of the Affordable Care Act and section 504 of the Rehabilitation Act of 1973.

g. Proposed Oral Notice

Pursuant to the statutory requirement at section 1866(a)(1)(Y)(i) of the Act, we are proposing under proposed new § 489.20(y)(2) that hospitals and CAHs provide an oral explanation of the written notice furnished to individuals who receive observation services as outpatients. We will provide guidance for oral notification in our forthcoming Medicare manual provisions. Hospitals and CAHs are familiar with providing oral explanations of written notices (for example, surgical and procedural consent notices and the Important Message from Medicare), and we expect that oral notification will occur in conjunction with delivery of the MOON. Again, hospitals and CAHs are reminded that recipients of Federal financial assistance have an independent obligation to provide language assistance services to individuals with LEP consistent with section 1557 of the Affordable Care Act and Title VI of the Civil Rights Act of 1964. In addition, recipients of Federal financial assistance have an independent obligation to provide auxiliary aids and services to individuals with disabilities free of charge, subject to section 1557 of the Affordable Care Act and section 504 of the Rehabilitation Act of 1973.

h. Proposed Signature Requirements

As set forth at section 1866(a)(1)(Y)(ii)(IV) of the Act, the written notification must be either signed by the individual receiving observation services as an outpatient or a person acting on such individual's behalf to acknowledge receipt of notification. Moreover, the statute provides that if such individual or person refuses to provide a signature, the written notification is to be signed by the staff member of the hospital or CAH who presented the written notification and certain information needs to be included with such signature. Accordingly, we are proposing under proposed new § 489.20(y)(3), that the written notice be signed, as described above, in order to acknowledge receipt and understanding of the notice. The MOON would include a dedicated signature area for this purpose. In cases where the individual receiving the MOON refuses to sign the notice, we are proposing that the MOON must be signed by the staff member who presents the notice to the individual. The staff signature would include the staff member's name and title, a certification statement that the notice was presented, and the date and time that the notice was presented.

i. No Appeal Rights Under the NOTICE Act

Section 1866(a)(1)(Y) of the Act, as added by the NOTICE Act, does not afford appeal rights to beneficiaries regarding the notice provided pursuant to that statutory provision. To provide clarity to this point, we are proposing to amend the regulations at 42 CFR 405.926 relating to actions that are not initial determinations, by adding new paragraph (u) to explain that issuance of the MOON by a hospital or CAH does not constitute an initial determination and therefore does not trigger appeal rights under 42 CFR part 405, subpart I.

M. Proposed Technical Changes and Correction of Typographical Errors in Certain Regulations Under 42 CFR Part 413 Relating to Costs to Related Organizations and Medicare Cost Reports

1. General Background

As part of our ongoing review of the Medicare regulations, we have identified a number of technical changes or corrections of typographical errors in 42 CFR part 413 relating to costs to related organizations and Medicare cost reports that need to be made. Below we are summarizing these proposed changes or corrections.

2. Proposed Technical Change to Regulations at 42 CFR 413.17(d)(1) on Cost to Related Organizations

Prior to the enactment of section 911(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), a provider had the right to nominate a fiscal intermediary (currently known as a Medicare Administrative Contractor (MAC) and referred to in this section as a "contractor") of its choice. Public Law 108–173 repealed the nomination provisions formerly found in section 1816 of the Act and added section 1874A (Contracts with Medicare Administrative Contractors). Currently, a provider will be assigned to the contractor that covers the geographic locale where the provider is located, as specified in the regulations at 42 CFR 421.404(b).

Because a provider is no longer permitted to select a contractor of its choice, and a contractor is now assigned to a provider, the parenthetical language of the regulation text at 42 CFR 413.17(d)(1) referring to a provider's nomination of a contractor is obsolete. Therefore, we are proposing to revise § 413.17(d)(1) to remove the parenthetical reference to a provider's nomination of a contractor.

3. Proposed Changes to 42 CFR 413.24(f)(4)(i) Relating to Electronic Submission of Cost Reports

In § 413.24(f)(4)(i), we incorrectly refer to a "Federally qualified health clinic." The correct entity title under section 1861(aa) of the Act is "Federally qualified health center." In this proposed rule, we are proposing to correct this error.

In addition, § 413.200(c)(1)(i) requires a histocompatibility laboratory to file a Medicare cost report in accordance with the regulations at § 413.24(f). For cost reporting periods ending on or after March 31, 2005, organ procurement organizations (OPOs) and histocompatibility laboratories are required to submit Medicare cost reports in a standardized electronic format, but histocompatibility laboratories were inadvertently omitted from the list of providers in the regulations text at § 413.24(f). As evidenced by the reference in the August 22, 2003 **Federal Register** document (68 FR 50720) to the Office of Management and Budget (OMB) approval number 0938–0102 of the Paperwork Reduction Act request for the cost reporting form entitled "Organ Procurement Agency/Laboratory Statement of Reimbursable Costs," histocompatibility laboratories were intended to be included in the regulation text. Both OPOs and histocompatibility laboratories have used that Medicare cost report form to report their statements of reimbursable costs since its approval by OMB for use for cost reporting periods ending on or after March 31, 2005. To correct this omission, we are proposing a technical change to § 413.24(f)(4)(i) to add "histocompatibility laboratories" to the list of providers required to submit cost reports in a standardized electronic format.

4. Proposed Technical Changes to 42 CFR 413.24(f)(4)(ii) Relating to Electronic Submission of Cost Reports and Due Dates

In this proposed rule, we are proposing a technical correction in § 413.24(f)(4)(ii) to the effective date for the submission of Medicare cost reports in a standardized electronic format for skilled nursing facilities (SNFs) and home health agencies (HHAs) from cost reporting periods ending on or after December 31, 1996 to cost reporting periods ending on or after February 1, 1997 to accurately reflect the regulation text finalized in the January 2, 1997 final rule, "Medicare Program: Electronic Cost Reporting for Skilled Nursing Facilities and Home Health Agencies," published in **Federal Register** at 62 FR 26 through 31.

For the same reasons articulated in section IV.M.3. of the preamble of this proposed rule, we also are proposing to revise § 413.24(f)(4)(ii) by adding histocompatibility laboratories to the list of providers required to file electronic cost reports. To correct a typographic error, we are proposing to remove the duplicate word "contractor" from the second sentence of this paragraph.

5. Proposed Technical Changes to 42 CFR 413.24(f)(4)(iv) Relating to Reporting Entities, Cost Report Certification Statement, Electronic Submission and Cost Reports Due Dates

In this proposed rule, we are proposing to revise § 413.24(f)(4)(iv) to make a technical correction to the effective date for SNFs and HHAs to submit hard copies of a settlement summary, a statement of certain worksheet totals found within the electronic file, and a certifying statement signed by its administrator or chief financial officer, from cost reporting periods ending on or after December 31, 1996, to cost reporting periods ending on or after February 1, 1997, to accurately reflect the regulation text finalized in the January 2, 1997 final rule (62 FR 26 through 31).

We are proposing to revise § 413.24(f)(4)(iv) by adding histocompatibility laboratories to the list of providers required to file electronic cost reports for the same reasons provided in section IV.M.3. of the preamble of this proposed rule. In addition, we are proposing to add histocompatibility laboratories to the list of providers required to submit hard copies of a settlement summary, a statement of certain worksheet totals found within the electronic file, and a certifying statement signed by its administrator or chief financial officer, for cost reporting periods ending on or after March 31, 2005, for the same reasons.

We also are proposing to correct a typographical error that occurred in the Medicare cost report certification statement set forth in § 413.24(f)(4)(iv) by adding the word "and" between the words "Sheet" and "Statement" to denote the two separate financial documents required to be submitted with the cost report; that is, the Balance Sheet and the Statement of Revenue and Expenses. The cost report certification statement historically correctly denoted the two separate and distinct financial forms, the Balance Sheet and the Statement of Revenue and Expenses on Worksheet S (Form CMS–2552–92) of the Medicare cost report since the Worksheet S was first used in 1993. The Medicare cost report certification statement was later incorporated into § 413.24(f)(4)(iv) in a final rule with comment period (59 FR 26964 through 26965) issued in response to public comments received following the Uniform Electronic Cost Reporting System for Hospitals proposed rule (56 FR 41110). A typographical error excluding the word "and" occurred during the incorporation of the certification statement into the regulations text at § 413.24(f)(4)(iv).

6. Proposed Technical Correction to 42 CFR 413.200(c)(1)(i) Relating to Medicare Cost Report Due Dates for Organ Procurement Organizations and Histocompatibility Laboratories

In this proposed rule, we are proposing to make a technical correction to the reference in § 413.200(c)(1)(i) to the due date for the Medicare cost report for organ procurement organizations (OPOs) and histocompatibility laboratories from "three months" to "5 months" after the end of the fiscal year. Section 413.200(c)(1)(i) requires independent OPOs and histocompatibility laboratories to file a cost report in accordance with § 413.24(f). In the 1995 final rule (60 FR 33137), we revised § 413.24(f) to extend the Medicare cost report due date for all providers required to file a cost report from 3 months to 5 months after the end of a provider's fiscal year end, but inadvertently neglected to make a conforming change to § 413.200(c)(1)(i), which we are proposing to correct in this proposed rule.

N. Clarification Regarding the Medicare Utilization Requirement for Medicare-Dependent, Small Rural Hospitals (MDHs) (§ 412.108)

1. Background

Section 1886(d)(5)(G) of the Act provides special payment protections under the IPPS to Medicare-dependent, small rural hospitals (MDHs). (For additional information on the MDH program and the payment methodology, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684).) As we discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50287) and in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684), section 3124 of the Affordable Care Act extended the expiration of the MDH program from the end of FY 2011 (that is, for discharges occurring before October 1, 2011) to the end of FY 2012 (that is, for discharges occurring before October 1, 2012). Under prior law, as specified in section 5003(a) of Public Law 109–171 (DRA 2005), the MDH program was to be in effect through the end of FY 2011 only.

Since the extension of the MDH program through FY 2012 provided by section 3124 of the Affordable Care Act, the MDH program has been further extended multiple times. First, section 606 of the ATRA (Public L. 112–240) extended the MDH program through FY 2013 (that is, for discharges occurring before October 1, 2013). Second, section 1106 of the Pathway for SGR Reform Act of 2013 (Public L. 113–67) extended the MDH program through the first half of FY 2014 (that is, for discharges occurring before April 1, 2014). Third, section 106 of the PAMA (Public L. 113–93) extended the MDH program through the first half of FY 2015 (that is, for discharges occurring before April 1, 2015). Fourth and most recently, section 205 of the MACRA (Public L. 114–10) extended the MDH program through FY 2017 (that is, for discharges occurring before October 1, 2017). For additional information on the extensions of the MDH program after FY 2012, we refer readers to the following **Federal Register** documents: The FY 2013 IPPS/LTCH PPS final rule (77 FR 53404 through 53405 and 53413 through 53414); the FY 2013 IPPS notice (78 FR 14689); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50647 through 50649); the FY 2014 IPPS interim final rule with comment period (79 FR 15025 through 15027); the FY 2014 IPPS notice (79 FR 34446 through 34449); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50022 through 50024); and the FY 2016 interim final rule with comment period (80 FR 49596 through 49597).

2. Clarification of Medicare Utilization Criterion for MDH Classification

Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area, has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (that is, not less than 60 percent of its inpatient days or discharges during the cost reporting period beginning in FY 1987 or two of the three most recently audited cost reporting periods for which the Secretary has a settled cost report were attributable to inpatients entitled to benefits under Part A). The regulations at 42 CFR 412.108 set forth the criteria that a hospital must meet to be classified as an MDH.

The Medicare utilization requirement is set forth at section 1886(d)(5)(G)(iv)(IV) of the Act and implemented by regulation at 42 CFR 412.108(a)(1)(iii). Consistent with the policy noted in the FY 1991 IPPS final rule (55 FR 35995) and further discussed in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50287), in order to not disadvantage hospitals that receive payment from a Medicare Advantage (MA) organization under Medicare Part C for inpatient care provided to Medicare beneficiaries enrolled in Medicare Part C plans, we count the days and discharges for those stays toward the 60-percent Medicare utilization requirement for MDH classification.

In accordance with the regulations at § 412.108(b)(5), Medicare contractors (MACs) evaluate, on an ongoing basis, whether or not a hospital continues to qualify for MDH status. For hospitals that qualify for MDH status under § 412.108(a)(1)(iii)(C) and in accordance with the regulations at § 412.108(b)(5), at each cost report settlement, the MAC will determine whether the hospital has a Medicare utilization of at least 60 percent in at least two of the last three most recent audited cost reports for which the Secretary has a settled cost report by including the newly settled cost report in the evaluation.

Medicare policy requires hospitals that receive certain additional payments such as IME, direct GME, and DSH, to submit claims for services furnished to individuals enrolled in a MA plan under Medicare Part C. Specifically, teaching hospitals that provide services to individuals enrolled in a MA plan under Medicare Part C must submit timely claims in order to receive the supplemental IME and direct GME payments for services provided to these individuals. Likewise, hospitals that operate nursing or allied health education programs and incur costs associated with individuals enrolled in a MA plan under Medicare Part C also must submit timely claims in order to receive the additional payment amount for those MA enrollees. In addition, hospitals that are eligible for DSH payments are required to submit claims in a timely manner for individuals enrolled in a MA plan under Medicare Part C in order for these days to be captured in the DSH calculation. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53409) for more information and background on the requirements for filing no pay bills for services furnished to individuals enrolled in a MA plan under Medicare Part C.

Consistent with this policy, for a hospital that is eligible for IME, direct GME, or DSH payments, CMS only includes MA days or discharges as reported on the cost report and verified by the properly and timely submitted claims for the services furnished to individuals enrolled in a MA plan under Medicare Part C associated with those days or discharges in calculating Medicare utilization for MDH purposes. CMS verifies the accuracy of the MA days and discharges reported on the cost report using claims data; once verified, the cost report data can then be properly applied in the Medicare utilization calculation.

For a hospital that is not eligible for IME, direct GME, or DSH payments and is not required to submit bills for services furnished to individuals enrolled in a MA plan under Medicare Part C, we are clarifying that CMS will include the MA days or discharges associated with those services in the Medicare utilization calculation, regardless of whether the hospital submitted claims for services associated with those days or discharges provided that the hospital submits proper documentation, such as provider logs, that allow the MAC to verify the MA days or discharges as reported on the hospital's cost report. However, we note that, while not required, timely submission of claims for the services furnished to individuals enrolled in a MA plan under Medicare Part C allows CMS to establish whether the hospital meets the MDH classification criteria in an expeditious and timely manner.

O. Adjustment to IPPS Rates Resulting From 2-Midnight Policy

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50906 through 50954), we adopted the 2-midnight policy, effective for dates of admission on or after October 1, 2013. Under the 2-midnight policy, an inpatient admission is generally appropriate for Medicare Part A payment if the physician (or other qualified practitioner) admits the patient as an inpatient based upon the reasonable expectation that the patient will need hospital care that crosses at least 2 midnights. In assessing the expected duration of necessary care, the physician (or other qualified practitioner) may take into account outpatient hospital care received prior to inpatient admission. If the patient is expected to need less than 2 midnights of care in the hospital, the services furnished should generally be billed as outpatient services. We note that revisions were made to this policy in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70545). Our actuaries estimated that the 2-midnight policy would increase expenditures by approximately $220 million in FY 2014 due to an expected net increase in inpatient encounters. We used our authority under section 1886(d)(5)(I)(i) of the Act to make a reduction of 0.2 percent to the standardized amount, the Puerto Rico standardized amount, and the hospital-specific payment rates, and we used our authority under section 1886(g) of the Act to make a reduction of 0.2 percent to the national capital Federal rate and the Puerto Rico-specific capital rate, in order to offset this estimated $220 million in additional IPPS expenditures in FY 2014. We indicated that although our exceptions and adjustments authority should not be routinely used in the IPPS system, we believed that the systemic and widespread nature of this issue justified an overall adjustment to the IPPS rates and such an adjustment is authorized under section 1886(d)(5)(I)(i) of the Act.

In *Shands Jacksonville Medical Center, Inc.* v. *Burwell,* No. 14–263 (D.D.C.) and consolidated cases, hospitals challenged the 0.2 percent reduction in IPPS rates to account for the estimated $220 million in additional FY 2014 expenditures resulting from the 2-midnight policy. In its Memorandum Opinion, issued September 21, 2015, the Court found that the "Secretary's interpretation of the exceptions and adjustments provision is a reasonable one" for this purpose. However, the Court also ordered the 0.2 percent reduction remanded back to the Secretary, without vacating the rule, to correct certain procedural deficiencies in the promulgation of the 0.2 percent reduction and reconsider the adjustment. The Court did not believe it would be appropriate to vacate the rule because such action would, in effect, dictate a substantive outcome based on a procedural error and concluded that the disruptive consequences would be considerable.

In accordance with the Court's order, we published a notice with comment period that appeared in the December 1, 2015 **Federal Register** (80 FR 75107), which discussed the basis for the 0.2 percent reduction and its underlying assumptions and invited comments on the same in order to facilitate our further consideration of the FY 2014 reduction. We received numerous public comments on the notice with comment period.

In considering these public comments, and those on the same topic received in response to the CY 2016 OPPS/ASC proposed rule, we continue to recognize that the 0.2 percent reduction issue is unique in many ways. The underlying question of patient status, which resulted in the creation of the 2-midnight policy, is a complex one with a long history, including large improper payment rates in short-stay hospital inpatient claims, requests to provide additional guidance regarding the proper billing of those services, and concerns about increasingly long stays of Medicare beneficiaries as outpatients due to hospital uncertainties about payment. (For further discussion of this history, we refer readers to the FY 2014 IPPS/LTCH PPS proposed and final rules (78 FR 27644 through 27649 and 78 FR 50906 through 50954, respectively).)

The 2-midnight policy itself and our implementation and enforcement of it have also evolved over time as a result of a combination of statutory, regulatory, and operational changes. For example, as part of our efforts to provide education to stakeholders on the new 2-midnight policy, CMS hosted numerous "Open Door Forums," conducted national provider calls, and shared information and answers to frequently asked questions on the CMS Web site. In addition, we instructed MACs to conduct a "Probe and Educate" process for inpatient claims with dates of admission on or after October 1, 2013 through September 30, 2014, to assess provider understanding and compliance with the new 2-midnight policy. We also prohibited Recovery Auditor's post-payment medical reviews of inpatient hospital patient status for claims with dates of admission between October 1, 2013 and September 30, 2014.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93) was enacted. Section 111 of Public Law 113–93 permitted CMS to continue medical review activities under the Inpatient Probe and Educate process through March 31, 2015. The same law also extended the prohibition on Recovery Auditor reviews of inpatient hospital patient status for claims with dates of admission through March 31, 2015, absent evidence of systematic gaming, fraud, abuse, or delays in the provision of care by a provider of services. On April 16, 2015, the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10) was enacted. Section 521 of Public Law 114–10 permitted CMS to further extend the medical review activities under the Inpatient Probe and Educate process for inpatient claims through September 30, 2015, and extended the prohibition of Recovery Auditor reviews of inpatient hospital patient status for claims with dates of admission through September 30, 2015. CMS then announced in August 2015 that it would not approve Recovery Auditors to conduct patient status reviews for dates of admission of October 1, 2015 through December 31, 2015.

As we indicated in the CY 2016 OPPS/ASC final rule with comment period, throughout the Probe and Educate process, we saw positive effects and improved provider understanding of the 2-midnight policy. We also discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70545 through 70549) a number of additional changes we had made and were continuing to make to the Recovery Audit Program and changes to the medical review responsibilities for Quality Improvement Organizations (QIOs) in regard to short hospital stay claims.

With respect to the 2-midnight policy itself, in light of stakeholder concerns and in our continued effort to develop the most appropriate and applicable framework for determining when payment under Medicare Part A is appropriate for inpatient admissions, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70545), we modified the original "rare and unusual" exceptions policy under the 2-midnight policy to allow for Medicare Part A payment on a case-by-case basis for inpatient admissions that do not satisfy the 2-midnight benchmark, if the documentation in the medical record supports the admitting physician's determination that the patient requires inpatient hospital care despite an expected length of stay that is less than 2 midnights.

We also recognized in reviewing the public comments we received on the 0.2 percent reduction in response to the December 1, 2015 notice with comment period and the CY 2016 OPPS/ASC proposed rule that, in addition to the long history of the question of patient status underlying the 2-midnight policy and the statutory, regulatory, and operational changes that have occurred since its initial implementation, the original estimate for the 0.2 percent reduction had a much greater degree of uncertainty than usual. As indicated in the Office of the Actuary's August 19, 2013 memorandum (which was included as Appendix A of the December 1, 2015 notice with comment period (80 FR 75112 through 75114)), the estimate depended critically on the assumed utilization changes in the inpatient and outpatient hospital settings, relatively small changes would have a disproportionate effect on the estimated net costs, the estimate was subject to a much greater degree of uncertainty than usual, and the actual results could differ significantly from the estimate.

Lastly, in reviewing the public comments we received on the December 1, 2015 notice with comment period, we also considered the fact that our actuaries' most recent estimate of the impact of the 2-midnight policy varies between a savings and a cost over the FY 2014 to FY 2015 time period. The memorandum describing this new analysis is available on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

We still believe the assumptions underlying the 0.2 percent reduction to the rates put in place beginning in FY 2014 were reasonable at the time we made them in 2013. Nevertheless, taking all the foregoing factors into account, in the context of this case, we believe it would be appropriate to use our authority under sections 1886(d)(5)(I)(i) and 1886(g) of the Act to prospectively remove, beginning in FY 2017, the 0.2 percent reduction to the rates put in place beginning in FY 2014. The 0.2 percent reduction was implemented by including a factor of 0.998 in the calculation of the FY 2014 standardized amount, the hospital-specific payment rates, and the national capital Federal rate, permanently reducing the rates for FY 2014 and future years until the 0.998 is removed. We are proposing to permanently remove the 0.998 reduction beginning in FY 2017 by including a factor of (1/0.998) in the calculation of the FY 2017 standardized amount, the hospital-specific payment rates, and the national capital Federal rate.

In addition, taking all the foregoing factors into account, and given the unique nature of this situation in which the court has ordered us to further explain the assumptions underlying an adjustment applicable to past years, we believe it would be appropriate to use our authority under sections 1886(d)(5)(I)(i) and 1886(g) of the Act to temporarily increase the rates, only for FY 2017, to address the effect of the 0.2 percent reduction to the rates in effect for FY 2014, the 0.2 reduction to the rates in effect for FY 2015 (recall the 0.998 factor included in the calculation of the FY 2014 rates permanently reduced the rates for FY 2014 and future years until it is removed), and the 0.2 reduction to the rates in effect for FY 2016. We believe that the most transparent, expedient, and administratively feasible method to accomplish this is a temporary one-time prospective increase to the FY 2017 rates of 0.6 percent (= 0.2 percent + 0.2 percent + 0.2 percent). Specifically, we are proposing to include a factor of 1.006 in the calculation of the standardized amount, the hospital-specific payment rates, and the national capital Federal rate in FY 2017 and then remove this temporary one-time prospective increase by including a factor of (1/1.006) in the calculation of the rates for FY 2018. While we generally do not believe it is appropriate in a prospective system to retrospectively adjust rates even where we believe a prospective change in policy is warranted, we take this action in the specific context of this unique situation, in which we have been ordered by a Federal court to further explain the basis of an adjustment we have imposed for past years.

In summary, for the reasons described above, we are proposing to include a permanent factor of (1/0.998) and a temporary one-time factor of (1.006) in the calculation of the FY 2017 standardized amount, the hospital-specific payment rates, and the national capital Federal rate. We also are proposing to include a factor of (1/1.006) in the calculation of the FY 2018 standardized amount, the hospital-specific payment rates, and the national capital Federal rate to remove the temporary one-time factor of 1.006.

We are inviting public comments on all aspects these proposals. The foregoing discussion and proposals constitute the final notice required by the Court in the *Shands Jacksonville Medical Center, Inc.* v. *Burwell*, No. 14–263 (D.D.C.) and consolidated cases.

V. Proposed Changes to the IPPS for Capital-Related Costs

A. Overview

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient acute hospital services in accordance with a prospective payment system established by the Secretary. Under the statute, the Secretary has broad authority in establishing and implementing the IPPS for acute care hospital inpatient capital-related costs. We initially implemented the IPPS for capital-related costs in the Federal fiscal year (FY) 1992 IPPS final rule (56 FR 43358). In that final rule, we established a 10-year transition period to change the payment methodology for Medicare hospital inpatient capital-related costs from a reasonable cost-based payment methodology to a prospective payment methodology (based fully on the Federal rate).

FY 2001 was the last year of the 10-year transition period that was established to phase in the IPPS for hospital inpatient capital-related costs. For cost reporting periods beginning in FY 2002, capital IPPS payments are based solely on the Federal rate for almost all acute care hospitals (other than hospitals receiving certain exception payments and certain new hospitals). (We refer readers to the FY 2002 IPPS final rule (66 FR 39910 through 39914) for additional information on the methodology used to determine capital IPPS payments to hospitals both during and after the transition period.)

The basic methodology for determining capital prospective payments using the Federal rate is set forth in the regulations at 42 CFR 412.312. For the purpose of calculating capital payments for each discharge, the standard Federal rate is adjusted as follows:

(Standard Federal Rate) × (DRG Weight) × (Geographic Adjustment Factor (GAF)) × (COLA for hospitals located in Alaska and Hawaii) × (1 + Capital DSH Adjustment Factor + Capital IME Adjustment Factor, if applicable).

In addition, under § 412.312(c), hospitals also may receive outlier payments under the capital IPPS for extraordinarily high-cost cases that qualify under the thresholds established for each fiscal year.

B. Additional Provisions

1. Exception Payments

The regulations at 42 CFR 412.348 provide for certain exception payments under the capital IPPS. The regular exception payments provided under §§ 412.348(b) through (e) were available only during the 10-year transition period. For a certain period after the transition period, eligible hospitals may have received additional payments under the special exceptions provisions at § 412.348(g). However, FY 2012 was the final year hospitals could receive special exceptions payments. For additional details regarding these exceptions policies, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725).

Under § 412.348(f), a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of $5 million due to extraordinary circumstances beyond the hospital's control. Additional information on the exception payment for extraordinary circumstances in § 412.348(f) can be found in the FY 2005 IPPS final rule (69 FR 49185 and 49186).

2. New Hospitals

Under the capital IPPS, the regulations at 42 CFR 412.300(b) define a new hospital as a hospital that has operated (under previous or current ownership) for less than 2 years and lists examples of hospitals that are not considered new hospitals. In accordance with § 412.304(c)(2), under the capital IPPS, a new hospital is paid 85 percent of its allowable Medicare inpatient hospital capital-related costs through its first 2 years of operation, unless the new hospital elects to receive full prospective payment based on 100 percent of the Federal rate. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725) for additional information on payments to new hospitals under the capital IPPS.

3. Proposed Changes in Payments for Hospitals Located in Puerto Rico

The regulations at 42 CFR 412.374 provide for the use of a blended payment amount for prospective payments for capital-related costs to hospitals located in Puerto Rico. Accordingly, under the capital IPPS, we currently compute a separate payment rate specific to Puerto Rico hospitals using the same methodology used to compute the national Federal rate for capital-related costs. The capital-related payment rate for hospitals located in Puerto Rico is derived using only the costs of hospitals located in Puerto Rico, while the national Federal rate for capital-related costs is derived using the costs of all acute care hospitals participating in the IPPS (including hospitals located in Puerto Rico). In general, hospitals located in Puerto Rico are paid a blend of the applicable capital IPPS Puerto Rico rate and the applicable capital IPPS Federal rate. Historically, we have established a capital IPPS blended payment rate structure for hospitals located in Puerto Rico that parallels the statutory calculation of operating IPPS payments to hospitals located in Puerto Rico. Capital IPPS payments to hospitals located in Puerto Rico are currently computed based on a blend of 25 percent of the capital IPPS Puerto Rico rate and 75 percent of the capital IPPS Federal rate. (For additional details on capital IPPS payments to hospitals located in Puerto Rico, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725).)

As noted in section IV.A. of the preamble of this proposed rule, section 601 of the Consolidated Appropriations Act, 2016 (Public L. 114–113) increased the applicable Federal percentage of the operating IPPS payment for hospitals located in Puerto Rico from 75 percent to 100 percent and decreased the applicable Puerto Rico percentage of the operating IPPS payments for hospitals located in Puerto Rico from 25 percent to zero percent, applicable to discharges occurring on or after January 1, 2016. Consistent with historical practice, under the broad authority of the Secretary granted under section 1886(g) of the Act, we are proposing to revise the calculation of capital IPPS payments to hospitals located in Puerto Rico to parallel the change in the statutory calculation of operating IPPS payments to hospitals located in Puerto Rico, beginning in FY 2017. Accordingly, we are proposing to revise § 412.374 of the regulations to provide that, for discharges occurring on or after October 1, 2016, capital IPPS payments to hospitals located in Puerto Rico would be based on 100 percent of the capital Federal rate; that is, payments would no longer be derived from a blend of the capital Puerto Rico rate and the capital Federal rate. As discussed in section I.I. of Appendix A (Economic Analyses) of this proposed rule, this proposed change would result in a slight increase in capital IPPS payments to hospitals located in Puerto Rico because adjusted capital IPPS payments based on the capital Federal rate are generally higher than capital IPPS payments based on the capital Puerto Rico rate. In addition, we note that this proposed change is similar to the changes in capital IPPS payments to hospitals located in Puerto Rico beginning in FY 1998 and FY 2005 that paralleled the corresponding statutory changes in the blended payment amount calculation required for operating IPPS payments to hospitals located in Puerto Rico, as provided by section 4406 of Public Law 105–33 (62 FR 46048) and section 504 of Public Law 108–173 (69 FR 49185), respectively.

C. Proposed Annual Update for FY 2017

The proposed annual update to the capital PPS Federal rate, as provided for at § 412.308(c), for FY 2017 is discussed in section III. of the Addendum to this proposed rule. Consistent with our proposal to revise the calculation of capital IPPS payments to hospitals located in Puerto Rico to be based on 100 percent of the capital Federal rate (and no longer based on a blend of the capital Puerto Rico rate and the capital Federal rate), we would discontinue use of the Puerto Rico capital rate in the calculation of capital IPPS payments to hospitals located in Puerto Rico.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50906 through 50954), we adopted the 2-midnight policy effective for dates of admission on or after October 1, 2013, under which an inpatient admission is generally appropriate for Medicare Part A payment if the physician (or other qualified practitioner) admits the patient as an inpatient based upon the reasonable expectation that the patient will need hospital care that crosses at least 2 midnights. At that time, our actuaries estimated that the 2-midnight policy would increase expenditures by approximately $220 million in FY 2014 due to an expected net increase in inpatient encounters. In that same final rule, consistent with the approach taken for the operating IPPS standardized amount, the Puerto Rico-specific standardized amount, and the hospital-specific payment rates, and using our authority under section 1886(g) of the Act, we made a reduction of 0.2 percent (an adjustment factor of 0.998) to the national capital Federal rate and the Puerto Rico-specific capital rate to offset the estimated increase in capital IPPS expenditures associated with the projected increase in inpatient encounters that was expected to result from the new inpatient admission guidelines (78 FR 50746 through 50747).

As discussed in section IV.O. of the preamble of this proposed rule, in *Shands Jacksonville Medical Center, Inc.* v. *Burwell,* No. 14–263 (D.D.C.) and consolidated cases, hospitals challenged the 0.2 percent reduction in IPPS rates to account for the estimated $220 million in additional FY 2014 expenditures resulting from the 2-midnight policy. In accordance with the Court's order, we published a notice with comment period that appeared in the December 1, 2015 **Federal Register** (80 FR 75107), which discussed the basis for the 0.2 percent reduction and its underlying assumptions and invited comments on the same in order to facilitate our further consideration of the FY 2014 reduction. In section IV.O. of the preamble of this proposed rule, we discuss that, in considering the public comments we received on that notice with comment period and those on the same topic we received in response to the CY 2016 OPPS/ASC proposed rule, we continue to recognize that the 0.2 percent reduction issue is unique in many ways. As we discuss in that section, the 2-midnight policy itself and our implementation and enforcement of it have also evolved over time as a result of a combination of statutory, regulatory, and operational changes. Finally, in reviewing the public comments received on the December 1, 2015 notice with comment period, we also considered the fact that our actuaries' most recent estimate of the impact of the 2-midnight policy varies between a savings and a cost over the FY 2014 to FY 2015 time period. (For additional details, we refer readers to section IV.O. of the preamble of this proposed rule.)

We still believe the assumptions underlying the 0.2 percent reduction to the rates put in place beginning in FY 2014 were reasonable at the time we made them in 2013. Nevertheless, taking all of these factors into account and in the context of this case, as we discuss in more detail in section IV.O. of the preamble of this proposed rule, consistent with the approach proposed for the operating IPPS rates, we believe it would be appropriate to use our authority under section 1886(g) of the Act to permanently remove the 0.2 percent reduction to the capital IPPS rate beginning in FY 2017. (As explained previously, we are proposing to discontinue use of the Puerto Rico capital rate in the calculation of capital IPPS payments to hospitals located in Puerto Rico beginning in FY 2017.) Specifically, we are proposing to make an adjustment of (1/0.998) to the national capital Federal rate to remove the 0.2 percent reduction, consistent with the proposed adjustment to the operating IPPS standardized amount and the hospital-specific payment rates. In addition, consistent with the approach proposed for the operating IPPS standardized amount and hospital-specific payment rates and for the reasons discussed in section IV.O. of the preamble of this proposed rule, we believe it would be appropriate to use our authority under section 1886(g) of the Act to adjust the FY 2017 capital IPPS rate to address the effects of the 0.2 percent reduction to the national capital Federal rates in effect for FY 2014, FY 2015, and FY 2016 by proposing a one-time prospective adjustment of 1.006 in FY 2017 to the national capital Federal rate. For FY 2018, we also are proposing to remove the effects of this one-time prospective adjustment through an adjustment of (1/1.006) to the national capital Federal rate, consistent with the approach proposed for the operating IPPS standardized amount and hospital-specific payment rates (as discussed in section IV.O. of the preamble of this proposed rule). We are inviting public comments on these proposals.

We also note that, in section II.D. of the preamble of this proposed rule, we present a discussion of the MS–DRG documentation and coding adjustment, including previously finalized policies and historical adjustments, as well as the recoupment adjustment to the standardized amounts under section 1886(d) of the Act that we are proposing for FY 2017 in accordance with the amendments made to section 7(b)(1)(B) of Public Law 110–90 by section 631 of the ATRA. Because section 631 of the ATRA requires us to make a recoupment adjustment only to the operating IPPS standardized amount, we are not proposing to make a similar adjustment to the capital IPPS rate (or to the operating IPPS hospital-specific rates). This approach is consistent with our historical approach regarding the application of the recoupment adjustment authorized by section 7(b)(1)(B) of Public Law 110–90.

VI. Proposed Changes for Hospitals Excluded From the IPPS

A. Proposed Rate-of-Increase in Payments to Excluded Hospitals for FY 2017

Certain hospitals excluded from a prospective payment system, including children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling. A per discharge limit (the target amount as defined in § 413.40(a) of the regulations) is set for each hospital based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. For each cost reporting period, the updated target amount is multiplied by total Medicare discharges during that period and applies as an aggregate upper limit (the ceiling as defined in § 413.40(a)) of Medicare reimbursement for total inpatient operating costs for a hospital's cost reporting period. In accordance with § 403.752(a) of the regulations, RNHCIs also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously.

As explained in the FY 2006 IPPS final rule (70 FR 47396 through 47398), beginning with FY 2006, we have used the percentage increase in the IPPS operating market basket to update the target amounts for children's hospitals, cancer hospitals, and RNHCIs. Consistent with §§ 412.23(g), 413.40(a)(2)(ii)(A), and 413.40(c)(3)(viii), we also have used the percentage increase in the IPPS operating market basket to update the target amounts for short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. As we finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50156 through 50157), for FY 2017, we will continue to use the percentage increase in the FY 2010-based IPPS operating market basket to update the target amounts for children's hospitals, cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. Accordingly, for FY 2017, the rate-of-increase percentage to be applied to the target amount for these children's hospitals, cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is the FY 2017 percentage increase in the FY 2010-based IPPS operating market basket.

For this FY 2017 proposed rule, based on IHS Global Insight, Inc.'s 2016 first quarter forecast, we estimate that the FY 2010-based IPPS operating market basket update for FY 2017 is 2.8 percent (that is, the estimate of the market basket rate-of-increase). Therefore, the FY 2017 rate-of-increase percentage that would be applied to the FY 2016 target amounts in order to calculate the FY 2017 target amounts for children's hospitals, cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is 2.8 percent, in accordance with the applicable regulations at 42 CFR 413.40. We are proposing that if more recent data become available for the final rule, we would use them to calculate the IPPS operating market basket update for FY 2017.

B. Critical Access Hospitals (CAHs)

1. Background

Section 1820 of the Act provides for the establishment of Medicare Rural Hospital Flexibility Programs (MRHFPs), under which individual States may designate certain facilities as critical access hospitals (CAHs). Facilities that are so designated and meet the CAH conditions of participation under 42 CFR part 485, subpart F, will be certified as CAHs by CMS. Regulations governing payments to CAHs for services to Medicare beneficiaries are located in 42 CFR part 413.

2. Frontier Community Health Integration Project (FCHIP) Demonstration

Section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275), as amended by section 3126 of the Affordable Care Act of 2010, authorizes a demonstration project to allow eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care and other health care services to

Medicare beneficiaries. The demonstration is titled "Demonstration Project on Community Health Integration Models in Certain Rural Counties," and is commonly known as the Frontier Community Health Integration Project (FCHIP) demonstration.

The authorizing statute states the eligibility criteria for entities to be able to participate in the demonstration. An eligible entity, as defined in section 123(d)(1)(B) of Public Law 110–275, as amended, is an MRHFP grantee under section 1820(g) of the Act (that is, a CAH); and is located in a State in which at least 65 percent of the counties in the State are counties that have 6 or less residents per square mile.

The authorizing statute stipulates several other requirements for the demonstration. Section 123(d)(2)(B) of Public. L. 110–275, as amended, limits participation in the demonstration to eligible entities in not more than 4 States. Section 123(f)(1) of Public. L. 110–275 requires the demonstration project to be conducted for a 3-year period. In addition, section 123(g)(1)(B) of Public. L. 110–275 requires that the demonstration be budget neutral. Specifically, this provision states that in conducting the demonstration project, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project under the section were not implemented. Furthermore, section 123(i) of Public. L. 110–275 states that the Secretary may waive such requirements of titles XVIII and XIX of the Act as may be necessary and appropriate for the purpose of carrying out the demonstration project, thus allowing the waiver of Medicare payment rules encompassed in the demonstration.

In January 2014, CMS released a request for applications (RFA) for the FCHIP demonstration. We refer readers to the RFA on the CMS Web site at: *https://innovation.cms.gov/initiatives/Frontier-Community-Health-Integration-Project-Demonstration/*. Using 2013 data from the U.S. Census Bureau, CMS identified Alaska, Montana, Nevada, North Dakota, and Wyoming as meeting the statutory eligibility requirement for participation in the demonstration. The RFA solicited CAHs in these five States to participate in the demonstration, stating that participation would be limited to CAHs in four of the States. To apply, CAHs were required to meet the eligibility requirements in the authorizing legislation, and, in addition, to describe a proposal to enhance health-related services that would complement those currently provided by the CAH and better serve the community's needs. In addition, in the RFA, CMS interpreted the eligible entity definition in the statute as meaning a CAH that receives funding through the Rural Hospital Flexibility Program. The RFA identified four intervention prongs, under which specific waivers of Medicare payment rules would allow for enhanced payment for telemedicine, nursing facility, ambulance, and home health services, respectively. These waivers were formulated with the goal of increasing access to care with no net increase in costs.

Since the due date for applications on May 5, 2014, we have assessed the feasibility of the applying CAHs' service delivery proposals, as well as the potential impacts of the payment enhancement interventions on the overall expenditures for Medicare services. We are selecting CAHs to participate in the demonstration, with the period of performance for each CAH expected to start August 1, 2016.

We have specified the payment enhancements for the demonstration, and are basing our selection of CAHs for participation, with the goal of maintaining the budget neutrality of the demonstration on its own terms (that is, the demonstration will produce savings from reduced transfers and admissions to other health care providers, thus offsetting any increase in payments resulting from the demonstration). However, because of the small size of this demonstration and uncertainty associated with projected Medicare utilization and costs, we are proposing a contingency plan to ensure that the budget neutrality requirement in section 123 of Public. L 110–275 is met. Accordingly, if analysis of claims data for Medicare beneficiaries receiving services at each of the participating CAHs, as well as of other data sources, including cost reports for these CAHs, shows that increases in Medicare payments under the demonstration during the 3-year period are not sufficiently offset by reductions elsewhere, we will recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide. Because of the small scale of the demonstration, we do not believe it would be feasible to implement budget neutrality by reducing payments to only the participating CAHs. Therefore, in the event that this demonstration is found to result in aggregate payments in excess of the amount that would have been paid if this demonstration were not implemented, we are proposing to comply with the budget neutrality requirement by reducing payments to all CAHs, not just those participating in the demonstration. We believe it is appropriate to make any payment reductions across all CAHs because the FCHIP demonstration is specifically designed to test innovations that affect delivery of services by the CAH provider category. We believe that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of Public. L. 110–275 permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented, and does not identify the range across which aggregate payments must be held equal.

Based on actuarial analysis using cost report settlements for FYs 2013 and 2014, the demonstration is projected to satisfy the budget neutrality requirement and likely yield a total net savings. We estimate that the total impact of the payment recoupment would be no greater than 0.03 percent of CAHs' total Medicare payments within 1 fiscal year (that is, Medicare Part A and Part B). For the FCHIP demonstration, the final budget neutrality estimates will be based on the demonstration period, which is August 1, 2016 through July 31, 2019. The demonstration is projected to impact payments to participating CAHs under both Medicare Part A and Part B. Thus, in the event that we determine that aggregate payments under the demonstration exceed the payments that would otherwise have been made, we are proposing that CMS would recoup payments through reductions of Medicare payments to all CAHs under both Medicare Part A and Part B.

Given the 3-year period of performance of the FCHIP demonstration and the time needed to conduct the budget neutrality analysis, we anticipate that, in the event the demonstration is found not to have been budget neutral, any excess costs would be recouped over a period of 3 cost reporting years, beginning in CY 2020. We are proposing a 3-year period for recoupment to allow for a reasonable timeframe for the payment reduction and to minimize any impact on CAHs' operations.

VII. Proposed Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2017

A. Background of the LTCH PPS

1. Legislative and Regulatory Authority

Section 123 of the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) as amended by section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) provides for payment for both the operating and capital-related costs of hospital inpatient stays in long-term care hospitals (LTCHs) under Medicare Part A based on prospectively set rates. The Medicare prospective payment system (PPS) for LTCHs applies to hospitals that are described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002.

Section 1886(d)(1)(B)(iv)(I) of the Act defines an LTCH as a hospital which has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days. Section 1886(d)(1)(B)(iv)(II) of the Act also provides an alternative definition of LTCHs: specifically, a hospital that first received payment under section 1886(d) of the Act in 1986 and has an average inpatient length of stay (as determined by the Secretary of Health and Human Services (the Secretary)) of greater than 20 days and has 80 percent or more of its annual Medicare inpatient discharges with a principal diagnosis that reflects a finding of neoplastic disease in the 12-month cost reporting period ending in FY 1997.

Section 123 of the BBRA requires the PPS for LTCHs to be a "per discharge" system with a diagnosis-related group (DRG) based patient classification system that reflects the differences in patient resources and costs in LTCHs.

Section 307(b)(1) of the BIPA, among other things, mandates that the Secretary shall examine, and may provide for, adjustments to payments under the LTCH PPS, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and a disproportionate share adjustment.

In the August 30, 2002 **Federal Register**, we issued a final rule that implemented the LTCH PPS authorized under the BBRA and BIPA (67 FR 55954). For the initial implementation of the LTCH PPS (FYs 2003 through FY 2007), the system used information from LTCH patient records to classify patients into distinct long-term care diagnosis-related groups (LTC–DRGs) based on clinical characteristics and expected resource needs. Beginning in FY 2008, we adopted the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) as the patient classification system used under the LTCH PPS. Payments are calculated for each MS–LTC–DRG and provisions are made for appropriate payment adjustments. Payment rates under the LTCH PPS are updated annually and published in the **Federal Register**.

The LTCH PPS replaced the reasonable cost-based payment system under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) for payments for inpatient services provided by an LTCH with a cost reporting period beginning on or after October 1, 2002. (The regulations implementing the TEFRA reasonable cost-based payment provisions are located at 42 CFR part 413.) With the implementation of the PPS for acute care hospitals authorized by the Social Security Amendments of 1983 (Pub. L. 98–21), which added section 1886(d) to the Act, certain hospitals, including LTCHs, were excluded from the PPS for acute care hospitals and were paid their reasonable costs for inpatient services subject to a per discharge limitation or target amount under the TEFRA system. For each cost reporting period, a hospital-specific ceiling on payments was determined by multiplying the hospital's updated target amount by the number of total current year Medicare discharges. (Generally, in this section of the preamble of this proposed rule, when we refer to discharges, we describe Medicare discharges.) The August 30, 2002 final rule further details the payment policy under the TEFRA system (67 FR 55954).

In the August 30, 2002 final rule, we provided for a 5-year transition period from payments under the TEFRA system to payments under the LTCH PPS. During this 5-year transition period, an LTCH's total payment under the PPS was based on an increasing percentage of the Federal rate with a corresponding decrease in the percentage of the LTCH PPS payment that is based on reasonable cost concepts, unless an LTCH made a one-time election to be paid based on 100 percent of the Federal rate. Beginning with LTCHs' cost reporting periods beginning on or after October 1, 2006, total LTCH PPS payments are based on 100 percent of the Federal rate.

In addition, in the August 30, 2002 final rule, we presented an in-depth discussion of the LTCH PPS, including the patient classification system, relative weights, payment rates, additional payments, and the budget neutrality requirements mandated by section 123 of the BBRA. The same final rule that established regulations for the LTCH PPS under 42 CFR part 412, subpart O, also contained LTCH provisions related to covered inpatient services, limitation on charges to beneficiaries, medical review requirements, furnishing of inpatient hospital services directly or under arrangement, and reporting and recordkeeping requirements. We refer readers to the August 30, 2002 final rule for a comprehensive discussion of the research and data that supported the establishment of the LTCH PPS (67 FR 55954).

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623), we implemented the provisions of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67), which mandated the application of the "site neutral" payment rate under the LTCH PPS for discharges that do not meet the statutory criteria for exclusion beginning in FY 2016. For cost reporting periods beginning on or after October 1, 2015, discharges that do not meet certain statutory criteria for exclusion are paid based on the site neutral payment rate. Discharges that do meet the statutory criteria continue to receive payment based on the LTCH PPS standard Federal payment rate. For more information on the statutory requirements of the Pathway for SGR Reform Act of 2013, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623).

Section 231 of Consolidated Appropriations Act, 2016 (Pub. L. 114–113), enacted December 18, 2015, provides for a temporary exception to the application of the site neutral payment rate for certain discharges representing severe wound care cases from specific LTCHs. We will address this statutory provision in a separate rulemaking.

2. Criteria for Classification as an LTCH

a. Classification as an LTCH

Under the regulations at § 412.23(e)(1), to qualify to be paid under the LTCH PPS, a hospital must have a provider agreement with Medicare. Furthermore, § 412.23(e)(2)(i), which implements section 1886(d)(1)(B)(iv)(I) of the Act, requires that a hospital have an average Medicare inpatient length of stay of greater than 25 days to be paid under the LTCH PPS. Alternatively, § 412.23(e)(2)(ii) states that, for cost reporting periods beginning on or after August 5, 1997, a hospital that was first excluded from the PPS in 1986 and can demonstrate that at least 80 percent of its annual Medicare inpatient discharges in the 12-month cost reporting period ending in FY 1997 have a principal diagnosis that reflects a finding of neoplastic disease must have an average inpatient length of stay for all patients, including both Medicare and non-Medicare inpatients, of greater than 20 days (referred to as "subclause (II)" LTCHs).

b. Hospitals Excluded From the LTCH PPS

The following hospitals are paid under special payment provisions, as described in § 412.22(c) and, therefore, are not subject to the LTCH PPS rules:

- Veterans Administration hospitals.
- Hospitals that are reimbursed under State cost control systems approved under 42 CFR part 403.
- Hospitals that are reimbursed in accordance with demonstration projects authorized under section 402(a) of the Social Security Amendments of 1967 (Pub. L. 90–248) (42 U.S.C. 1395b–1) or section 222(a) of the Social Security Amendments of 1972 (Pub. L. 92–603) (42 U.S.C. 1395b–1 (note)) (Statewide all-payer systems, subject to the rate-of-increase test at section 1814(b) of the Act).
- Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

3. Limitation on Charges to Beneficiaries

In the August 30, 2002 final rule, we presented an in-depth discussion of beneficiary liability under the LTCH PPS (67 FR 55974 through 55975). This discussion was further clarified in the RY 2005 LTCH PPS final rule (69 FR 25676). In keeping with those discussions, if the Medicare payment to the LTCH is the full LTC–DRG payment amount, consistent with other established hospital prospective payment systems, § 412.507 currently provides that an LTCH may not bill a Medicare beneficiary for more than the deductible and coinsurance amounts as specified under §§ 409.82, 409.83, and 409.87 and for items and services specified under § 489.30(a). However, under the LTCH PPS, Medicare will only pay for days for which the beneficiary has coverage until the short-stay outlier (SSO) threshold is exceeded. If the Medicare payment was for a SSO case (§ 412.529), and that payment was less than the full LTC–DRG payment amount because the beneficiary had insufficient remaining Medicare days, the LTCH is currently also permitted to charge the beneficiary for services delivered on those uncovered days (§ 412.507). In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49623), we amended our regulations to limit the charges that may be imposed on beneficiaries whose discharges are paid at the site neutral payment rate under the LTCH PPS. In section VII.G. of the preamble of this proposed rule, we are proposing to amend the existing regulations relating to the limitation on charges to address beneficiary charges for LTCH services provided by subclause (II) LTCHs as part of our proposed refinement of the payment adjustment for subclause II LTCHs under § 412.526. We also are proposing to amend the regulations under § 412.507 to clarify our existing policy that blended payments made to an LTCH during its transitional period (that is, payment for discharges occurring in cost reporting periods beginning in FY 2016 or 2017) are considered to be a site neutral payment rate payment.

4. Administrative Simplification Compliance Act (ASCA) and Health Insurance Portability and Accountability Act (HIPAA) Compliance

Claims submitted to Medicare must comply with both the Administrative Simplification Compliance Act (ASCA) (Pub. L. 107–105), and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–191). Section 3 of the ASCA requires that the Medicare Program deny payment under Part A or Part B for any expenses incurred for items or services for which a claim is submitted other than in an electronic form specified by the Secretary. Section 1862(h) of the Act (as added by section 3(a) of the ASCA) provides that the Secretary shall waive such denial in two specific types of cases and may also waive such denial in such unusual cases as the Secretary finds appropriate (68 FR 48805). Section 3 of the ASCA operates in the context of the HIPAA regulations, which include, among other provisions, the transactions and code sets standards requirements codified under 45 CFR parts 160 and 162 (generally known as the Transactions Rule). The Transactions Rule requires covered entities, including covered health care providers, to conduct certain electronic health care transactions according to the applicable transactions and code sets standards.

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of health information technology and promote nationwide health information exchange to improve health care. The Office of the National Coordinator for Health Information Technology (ONC) leads these efforts in collaboration with other agencies, including CMS and the Office of the Assistant Secretary for Planning and Evaluation (ASPE). Through a number of activities, including several open government initiatives, HHS is promoting the adoption of electronic health record (EHR) technology certified under the ONC Health Information Technology (HIT) Certification Program (*https://www.healthit.gov/policy-researchers-implementers/2015-edition-final-rule*) developed to support secure, interoperable, health information exchange. We believe that the use of certified EHRs by LTCHs (and other types of providers that are ineligible for the Medicare and Medicaid EHR Incentive Programs) can effectively and efficiently help providers improve internal care delivery practices, support the exchange of important information across care partners and during transitions of care, and enable the reporting of electronically specified clinical quality measures (eCQMs) (as described elsewhere in this proposed rule). In 2015, ONC released a document entitled "Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap" (available at: *https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf*). In the near term, the Roadmap focuses on actions that will enable individuals and providers across the care continuum to send, receive, find and use a common set of electronic clinical information at the nationwide level by the end of 2017. The Roadmap's goals also align with the Improving Medicare Post-Acute Care Transformation Act of 2014 (Pub. L. 113–185) (IMPACT Act), which requires assessment data to be standardized and interoperable to allow for exchange of the data. Moreover, the vision described in the Roadmap significantly expands the types of electronic health information, information sources, and information users well beyond clinical information derived from EHRs. The Roadmap identifies four critical pathways that health IT stakeholders should focus on now in order to create a foundation for long-term success: (1) Improve technical standards and implementation guidance for priority data domains and associated elements; (2) rapidly shift and align Federal, State, and commercial payment policies from fee-for-service to value-based models to stimulate the demand for interoperability; (3) clarify and align Federal and State privacy and security requirements that enable interoperability; and (4) align and promote the use of consistent policies and business practices that support interoperability and address those that impede interoperability, in coordination with stakeholders. To support of the goals of the Roadmap, ONC released the 2016 Interoperability Standards Advisory (available at: *https://www.healthit.gov/standards-advisory/2016*), which suggests some of the best available standards, terminology, and implementation guides as well as emerging standards to enable priority health information exchange functions. Providers, payers, and vendors are encouraged to take these "best available standards" into account as they implement interoperable health information exchange across the continuum of care.

B. Proposed Modifications to the Application of the Site Neutral Payment Rate (§ 412.522)

1. Background

Section 1206 of Pathway for SGR Reform Act (Pub. L. 113–67) mandated significant changes to the LTCH PPS beginning with LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2015. Specifically, section 1206 required the establishment of a site neutral payment rate (as an alternative to the LTCH PPS standard Federal payment rate) for Medicare inpatient discharges from an LTCH that fail to meet certain statutorily defined criteria. Discharges that meet the statutory criteria for exclusion from the site neutral payment rate continue to be paid based on the LTCH PPS standard Federal payment rate. Discharges that do not meet the statutory criteria for exclusion are paid based on the site neutral payment rate. We implemented the application of the site neutral payment rate in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623) and codified the requirements in the regulations at 42 CFR 412.522. The criteria for exclusion from the site neutral payment rate specified under section 1886(m)(6)(A)(ii) of the Act and as implemented at § 412.522(b) are as follows: (1) The discharge from the LTCH does not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation; (2) admission to the LTCH was immediately preceded by discharge from a subsection (d) hospital; and (3) the immediately preceding stay in a subsection (d) hospital included at least 3 days in an intensive care unit (ICU) (referred to as the ICU criterion) or the discharge from the LTCH is assigned to a MS–LTC–DRG based on the patient's receipt of ventilator services of at least 96 hours (referred to as the ventilator criterion). (We note that, for the remainder of this section VII. of this preamble, the phrase "LTCH PPS standard Federal payment rate case" refers to an LTCH PPS case that meets the criteria for exclusion from the site neutral payment rate as specified under § 412.522(a)(2), and the phrase "site neutral payment rate case" refers to an LTCH PPS case that does not meet the statutory patient-level criteria as specified under § 412.522(a)(1) and, therefore, is paid the applicable site neutral payment rate.)

2. Technical Correction of Definition of "Subsection (d) Hospital" for the Site Neutral Payment Rate (§ 412.503)

In the FY 2016 IPPS/LTCH PPS final rule, we implemented section 1206(a) of Public Law 113–67, which established the new dual payment rate structure under the LTCH PPS that began with LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2015. Section 1206(a) required the establishment of a site neutral payment rate (as an alternate to the LTCH PPS standard Federal payment rate) under the LTCH PPS for Medicare inpatient LTCH discharges that fail to meet certain statutorily defined criteria for exclusion. Discharges that meet the statutory criteria for exclusion from the site neutral payment rate continue to be paid based on the LTCH PPS standard Federal payment rate. Discharges that do not meet the statutory criteria for exclusion are paid based on the new site neutral payment rate. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623), we codified the requirements for the application of the site neutral payment rate under the LTCH PPS under the regulations at § 412.522. The statutory criteria for exclusion from the site neutral payment rate include a criterion that requires that the admission to the LTCH was immediately preceded by discharge from a "subsection (d) hospital." To implement this criterion for purposes of the application of the site neutral payment rate under § 412.522, we added a definition of a "subsection (d) hospital" under § 412.503 of the regulations. However, we made an inadvertent cross-reference error under § 412.503 by referencing "§ 412.526" (payment provisions to a subclause II LTCH) instead of referencing "§ 412.522" (application of site neutral payment) (80 FR 49767). That is, currently § 412.503 specifies that a subsection (d) hospital means "for purposes of § 412.526," when the language should have read "for purposes of § 412.522". Therefore, we are proposing to revise § 412.503 to correct this cross-reference error.

C. Proposed Medicare Severity Long-Term Care Diagnosis-Related Group (MS–LTC–DRG) Classifications and Relative Weights for FY 2017

1. Background

Section 123 of the BBRA required that the Secretary implement a PPS for LTCHs to replace the cost-based payment system under TEFRA. Section 307(b)(1) of the BIPA modified the requirements of section 123 of the BBRA by requiring that the Secretary examine the feasibility and the impact of basing payment under the LTCH PPS on the use of existing (or refined) hospital DRGs that have been modified to account for different resource use of LTCH patients.

When the LTCH PPS was implemented for cost reporting periods beginning on or after October 1, 2002, we adopted the same DRG patient classification system utilized at that time under the IPPS. As a component of the LTCH PPS, we refer to this patient classification system as the "long-term care diagnosis-related groups (LTC–DRGs)." Although the patient classification system used under both the LTCH PPS and the IPPS are the same, the relative weights are different. The established relative weight methodology and data used under the LTCH PPS result in relative weights under the LTCH PPS that reflect the differences in patient resource use of LTCH patients, consistent with section 123(a)(1) of the BBRA (Pub. L. 106–113).

As part of our efforts to better recognize severity of illness among patients, in the FY 2008 IPPS final rule with comment period (72 FR 47130), the MS–DRGs and the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) were adopted under the IPPS and the LTCH PPS, respectively, effective beginning October 1, 2007 (FY 2008). For a full description of the development, implementation, and rationale for the use of the MS–DRGs and MS–LTC–DRGs, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47141 through 47175 and 47277 through 47299). (We note that, in that same final rule, we revised the regulations at § 412.503 to specify that for LTCH discharges occurring on or after October 1, 2007, when applying the provisions of 42 CFR part 412, subpart O applicable to LTCHs for policy descriptions and payment calculations, all references to LTC–DRGs would be considered a reference to MS–LTC–DRGs. For the remainder of this section, we present the discussion in terms of the current MS–LTC–DRG patient classification system unless specifically referring to the previous LTC–DRG patient classification system that was in effect before October 1, 2007.)

The MS–DRGs adopted in FY 2008 represent an increase in the number of DRGs by 207 (that is, from 538 to 745) (72 FR 47171). The MS–DRG classifications are updated annually. There are currently 758 MS–DRG groupings. For FY 2017, there are 757 MS–DRG groupings that we are proposing in conjunction with all of the changes discussed in section II.F. of the preamble of this proposed rule. Consistent with section 123 of the BBRA, as amended by section 307(b)(1) of the BIPA, and § 412.515 of the regulations, we use information derived from LTCH PPS patient records to classify LTCH discharges into distinct MS–LTC–DRGs based on clinical characteristics and estimated resource needs. We then assign an appropriate weight to the MS–LTC–DRGs to account for the difference in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCHs. In this section of the proposed rule, we provide a general summary of our existing methodology for determining the proposed FY 2017 MS–LTC–DRG relative weights under the LTCH PPS.

In this proposed rule, in general, for FY 2017, we are using our existing methodology to determine the MS–LTC–DRG relative weights (as discussed in greater detail in section VII.C.3. of the preamble of this proposed rule). As we established when we implemented the dual rate LTCH PPS payment structure codified under § 412.522, beginning with FY 2016, the annual recalibration of the MS–LTC–DRG relative weights are determined: (1) Using only data from available LTCH PPS claims that would have qualified for payment under the new LTCH PPS standard Federal payment rate if that rate were in effect when claims data from time periods before the dual rate LTCH PPS payment structure applies were used to calculate the relative weights; and (2) using only data from available LTCH PPS claims that qualify for payment under the new LTCH PPS standard Federal payment rate when claims data from time periods after the dual rate LTCH PPS payment structure applies are used to calculate the relative weights (80 FR 49624). That is, under our current methodology, the MS–LTC–DRG relative weights are not used to determine the LTCH PPS payment for cases paid at the site neutral payment rate under § 412.522(c)(1) and data from cases paid at the site neutral payment rate or that would have been paid at the site neutral payment rate if the dual rate LTCH PPS payment structure had been in effect are not used to develop the relative weights. For the remainder of this discussion, we use the phrase "applicable LTCH cases" or "applicable LTCH data" when referring to the resulting claims data set used to calculate the relative weights (as described later in greater detail in section VII.C.3.c. of the preamble of this proposed rule). In addition, we are proposing to continue to exclude the data from all-inclusive rate providers and LTCHs paid in accordance with demonstration projects, as well as any Medicare Advantage claims from the MS–LTC–DRG relative weight calculations for the reasons discussed in section VII.C.3.c. of the preamble of this proposed rule.

Furthermore, for FY 2017, in using data from applicable LTCH cases to establish proposed MS–LTC–DRG relative weights, we are proposing to continue to establish low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs with less than 25 cases) using our quintile methodology in determining the proposed MS–LTC–DRG relative weights because LTCHs do not typically treat the full range of diagnoses as do acute care hospitals. Therefore, for purposes of determining the proposed relative weights for the large number of low-volume MS–LTC–DRGs, we are proposing to group all of the low-volume MS–LTC–DRGs into five quintiles based on average charges per discharge. Then, under our existing methodology, we are proposing to account for adjustments made to LTCH PPS standard Federal payments for short-stay outlier (SSO) cases (that is, cases where the covered length of stay at the LTCH is less than or equal to five-sixths of the geometric average length of stay for the MS–LTC–DRG), and we are proposing to make adjustments to account for nonmonotonically increasing weights, when necessary. The methodology is premised on more severe cases under the MS–LTC–DRG system requiring greater expenditure of medical care resources and higher average charges such that, in the severity levels within a base MS–LTC–DRG, the relative weights should increase monotonically with severity from the lowest to highest severity level. (We discuss each of these components of our MS–LTC–DRG relative weight methodology in greater detail in section VII.C.3.g. of the preamble of this proposed rule.)

2. Patient Classifications Into MS–LTC–DRGs

a. Background

The MS–DRGs (used under the IPPS) and the MS–LTC–DRGs (used under the LTCH PPS) are based on the CMS DRG structure. As noted previously in this section, we refer to the DRGs under the LTCH PPS as MS–LTC–DRGs although they are structurally identical to the MS–DRGs used under the IPPS.

The MS–DRGs are organized into 25 major diagnostic categories (MDCs), most of which are based on a particular organ system of the body; the remainder involve multiple organ systems (such as MDC 22, Burns). Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Surgical DRGs are assigned based on a surgical hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures by resource intensity. The GROUPER software program does not recognize all ICD–10–PCS procedure codes as procedures affecting DRG assignment. That is, procedures that are not surgical (for example, EKGs), or minor surgical procedures (for example, a biopsy of skin and subcutaneous tissue (procedure code 86.11)) do not affect the MS–LTC–DRG assignment based on their presence on the claim.

Generally, under the LTCH PPS, a Medicare payment is made at a predetermined specific rate for each discharge and that payment varies by the MS–LTC–DRG to which a beneficiary's stay is assigned. Cases are classified into MS–LTC–DRGs for payment based on the following six data elements:

- Principal diagnosis;
- Additional or secondary diagnoses;
- Surgical procedures;
- Age;
- Sex; and
- Discharge status of the patient.

Currently, for claims submitted on the 5010 format, up to 25 diagnosis codes and 25 procedure codes are considered for an MS–DRG assignment. This includes one principal diagnosis and up to 24 secondary diagnoses for severity of illness determinations. (For additional information on the processing of up to 25 diagnosis codes and 25 procedure codes on hospital inpatient claims, we refer readers to section II.G.11.c. of the preamble of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50127).)

Under HIPAA transactions and code sets regulations at 45 CFR parts 160 and

162, covered entities must comply with the adopted transaction standards and operating rules specified in Subparts I through S of Part 162. Among other requirements, by January 1, 2012, covered entities were required to use the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12N/005010X223, and Type 1 Errata to Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X233A1 for the health care claims or equivalent encounter information transaction (45 CFR 162.1102(c)).

HIPAA requires covered entities to use the applicable medical data code set requirements when conducting HIPAA transactions (45 CFR 162.1000). Currently, upon the discharge of the patient, the LTCH must assign appropriate diagnosis and procedure codes from the most current version of the Internal Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, both of which became effective October 1, 2015 (45 CFR 162.1002(c)(2) and (3)). For additional information on the implementation of the ICD–10 coding system, we refer readers to section II.F.1. of the preamble of this proposed rule. Additional coding instructions and examples are published in the AHA's *Coding Clinic for ICD–10–CM/PCS*.

To create the MS–DRGs (and by extension, the MS–LTC–DRGs), base DRGs were subdivided according to the presence of specific secondary diagnoses designated as complications or comorbidities (CCs) into one, two, or three levels of severity, depending on the impact of the CCs on resources used for those cases. Specifically, there are sets of MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a CC or a major complication or comorbidity (MCC). We refer readers to section II.D. of the FY 2008 IPPS final rule with comment period for a detailed discussion about the creation of MS–DRGs based on severity of illness levels (72 FR 47141 through 47175).

MACs enter the clinical and demographic information submitted by LTCHs into their claims processing systems and subject this information to a series of automated screening processes called the Medicare Code Editor (MCE). These screens are designed to identify cases that require further review before assignment into a MS–LTC–DRG can be made. During this process, certain cases are selected for further development (74 FR 43949).

After screening through the MCE, each claim is classified into the appropriate MS–LTC–DRG by the Medicare LTCH GROUPER software on the basis of diagnosis and procedure codes and other demographic information (age, sex, and discharge status). The GROUPER software used under the LTCH PPS is the same GROUPER software program used under the IPPS. Following the MS–LTC–DRG assignment, the Medicare contractor determines the prospective payment amount by using the Medicare PRICER program, which accounts for hospital-specific adjustments. Under the LTCH PPS, we provide an opportunity for LTCHs to review the MS–LTC–DRG assignments made by the Medicare contractor and to submit additional information within a specified timeframe as provided in § 412.513(c).

The GROUPER software is used both to classify past cases to measure relative hospital resource consumption to establish the MS–LTC–DRG relative weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the MedPAR file. The data in this file are used to evaluate possible MS–DRG and MS–LTC–DRG classification changes and to recalibrate the MS–DRG and MS–LTC–DRG relative weights during our annual update under both the IPPS (§ 412.60(e)) and the LTCH PPS (§ 412.517), respectively.

b. Proposed Changes to the MS–LTC–DRGs for FY 2017

As specified by our regulations at § 412.517(a), which require that the MS–LTC–DRG classifications and relative weights be updated annually, and consistent with our historical practice of using the same patient classification system under the LTCH PPS as is used under the IPPS, we are proposing to update the MS–LTC–DRG classifications effective October 1, 2016, through September 30, 2017 (FY 2017), consistent with the proposed changes to specific MS–DRG classifications presented in section II.F. of the preamble of this proposed rule. Accordingly, the proposed MS–LTC–DRGs for FY 2017 presented in this proposed rule are the same as the proposed MS–DRGs that would be used under the IPPS for FY 2017. In addition, because the proposed MS–LTC–DRGs for FY 2017 are the same as the proposed MS–DRGs for FY 2017, the other proposed changes that affect proposed MS–DRG (and by extension proposed MS–LTC–DRG) assignments under GROUPER Version 34.0 as discussed in section II.G. of the preamble of this proposed rule, including the proposed changes to the MCE software and the ICD–10–CM/PCS coding system, also would be applicable under the LTCH PPS for FY 2017. (We note the GROUPER Version 34 is based on ICD–10–CM/PCS diagnoses and procedure codes, consistent with the requirement to use ICD–10 beginning October 1, 2015.)

3. Development of the Proposed FY 2017 MS–LTC–DRG Relative Weights

a. General Overview of the Development of the MS–LTC–DRG Relative Weights

One of the primary goals for the implementation of the LTCH PPS is to pay each LTCH an appropriate amount for the efficient delivery of medical care to Medicare patients. The system must be able to account adequately for each LTCH's case-mix in order to ensure both fair distribution of Medicare payments and access to adequate care for those Medicare patients whose care is more costly (67 FR 55984). To accomplish these goals, we have annually adjusted the LTCH PPS standard Federal prospective payment system rate by the applicable relative weight in determining payment to LTCHs for each case. In order to make these annual adjustments under the dual rate LTCH PPS payment structure, beginning with FY 2016, we recalibrate the MS–LTC–DRG relative weighting factors annually using data from applicable LTCH cases (80 FR 49614 through 49617). Under this policy, the resulting MS–LTC–DRG relative weights would continue to be used to adjust the LTCH PPS standard Federal payment rate when calculating the payment for LTCH PPS standard Federal payment rate cases.

The established methodology to develop the proposed MS–LTC–DRG relative weights is generally consistent with the methodology established when the LTCH PPS was implemented in the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55991). However, there have been some modifications of our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity resulting from the adoption of the MS–LTC–DRGs, along with the change made in conjunction with the implementation of the dual rate LTCH PPS payment structure beginning in FY 21016 to use LTCH claims data from only LTCH PPS standard Federal payment rate cases (or LTCH PPS cases that would have qualified for payment under the LTCH PPS standard Federal payment rate if the dual rate LTCH PPS payment structure were in effect at the time of the discharge) that began in FY 2016. (For details on the modifications to our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47289 through 47295) and the FY 2009 IPPS final rule (73 FR 48542 through 48550). For details on the change in our historical methodology to use LTCH claims data only from LTCH PPS standard Federal payment rate cases to determine the MS–LTC–DRG relative weights, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49614 through 49617). Under the LTCH PPS, relative weights for each MS–LTC–DRG are a primary element used to account for the variations in cost per discharge and resource utilization among the payment groups (§ 412.515). To ensure that Medicare patients classified to each MS–LTC–DRG have access to an appropriate level of services and to encourage efficiency, we calculate a relative weight for each MS–LTC–DRG that represents the resources needed by an average inpatient LTCH case in that MS–LTC–DRG. For example, cases in an MS–LTC–DRG with a relative weight of 2 would, on average, cost twice as much to treat as cases in an MS–LTC–DRG with a relative weight of 1.

b. Development of the Proposed MS–LTC–DRG Relative Weights for FY 2017

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49625 through 49634), we presented our policies for the development of the MS–LTC–DRG relative weights for FY 2016.

In this proposed rule, we are proposing to continue to use our current methodology to determine the MS–LTC–DRG relative weights for FY 2017, including the application of established policies related to, the hospital-specific relative value methodology, the treatment of severity levels in the MS–LTC–DRGs, low-volume and no-volume MS–LTC–DRGs, adjustments for nonmonotonicity, the steps for calculating the MS–LTC–DRG relative weights with a budget neutrality factor, and only using data from applicable LTCH cases (which includes our policy of only using cases that would meet the criteria for exclusion from the site neutral payment rate (or, for discharges occurring prior to the implementation of the dual rate LTCH PPS payment structure, would have met the criteria for exclusion had those criteria been in effect at the time of the discharge)).

In this section, we present our proposed methodology for determining the proposed MS–LTC–DRG relative weights for FY 2017, and we discuss the effects of our proposed policies concerning the data used to determine the proposed FY 2017 MS–LTC–DRG relative weights on the various components of our existing methodology in the discussion that follows.

c. Data

For this proposed rule, to calculate the proposed MS–LTC–DRG relative weights for FY 2017, we obtained total charges from FY 2015 Medicare LTCH claims data from the December 2015 update of the FY 2015 MedPAR file, which are the best available data at this time, and we are proposing to use Version 34 of the GROUPER to classify LTCH cases. Consistent with our historical practice, we use those data and the proposed Version 34 of the MS–LTC–DRGs in establishing the proposed FY 2017 MS–LTC–DRG relative weights in this proposed rule. To calculate the proposed FY 2017 MS–LTC–DRG relative weights under the dual rate LTCH PPS payment structure, we are proposing to continue to use applicable LTCH data, which includes our policy of only using cases that meet the criteria for exclusion from the site neutral payment rate (or would have met the criteria had they been in effect at the time of the discharge) (80 FR 49624). Specifically, we are proposing to begin by first evaluating the LTCH claims data in the December 2015 update of the FY 2015 MedPAR file to determine which LTCH cases would meet the criteria for exclusion from the site neutral payment rate under § 412.522(b) had the dual rate LTCH PPS payment structure been in effect at the time of discharge. We identified the FY 2015 LTCH cases that were not assigned to proposed MS–LTC–DRGs 876, 880, 881, 882, 883, 884, 885, 886, 887, 894, 895, 896, 897, 945 and 946, which identify LTCH cases that do not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation; and that either—

- The admission to the LTCH was "immediately preceded" by discharge from a subsection (d) hospital and the immediately preceding stay in that subsection (d) hospital included at least 3 days in an ICU, as we define under the ICU criterion; or
- The admission to the LTCH was "immediately preceded" by discharge from a subsection (d) hospital and the claim for the LTCH discharge includes the applicable procedure code that indicates at least 96 hours of ventilator services were provided during the LTCH stay, as we define under the ventilator criterion. Claims data from the FY 2015 MedPAR file that reported ICD–9–CM procedure code 96.72 were used to identify cases involving at least 96 hours of ventilator services in accordance with the ventilator criterion (as FY 2015 discharges occurred prior to the adoption of ICD–10–CM/PCS). (We note that the corresponding ICD–10–PCS code for cases involving at least 94 hours of ventilation services is 5A1955Z, effective October 1, 2016) (80 FR 49626 through 49627). We note that, for purposes of developing the proposed FY 2017 MS–LTC–DRG relative weights using our current methodology, we did not identify any cases that would have been excluded from the site neutral payment rate under the temporary statutory provision for certain wound care discharges from certain LTCHs provided by Public Law 114–113 had the dual rate LTCH PPS payment structure been in effect at the time of the discharge. At this time, it is uncertain how many LTCHs and how many cases in the claims data we are using for this proposed rule would have met the statutory criteria to be excluded from the site neutral payment rate under that statutory provision (had the dual rate LTCH PPS payment structure been in effect at the time of the discharge). Therefore, for the remainder of this section, when we refer to LTCH claims only from cases that meet the criteria for exclusion from the site neutral payment rate (or would meet the criteria had they been in effect at the time of the discharge), such data do not include any cases that would have been paid based on the LTCH PPS standard Federal payment rate under the provisions of section 231 of Public Law 114–113, had the dual rate LTCH PPS payment structure been in effect at the time of the discharge.

Then, consistent with our historical methodology, we are proposing to exclude any claims in the resulting data set that were submitted by LTCHs that are all-inclusive rate providers and LTCHs that are reimbursed in accordance with demonstration projects authorized under section 402(a) of Public Law 90–248 or section 222(a) of Public Law 92–603. In addition, consistent with our historical practice, we would exclude the Medicare Advantage (Part C) claims that were in the resulting data set based on the presence of a GHO Paid indicator value of "1" in the MedPAR files. The claims that remained after these three trims (that is, the applicable LTCH data) were then used to calculate the proposed MS–LTC–DRG relative weights for FY 2017.

In summary, in general, in identifying the claims data for the development of the proposed FY 2017 MS–LTC–DRG relative weights in this proposed rule, we are proposing to use claims data after we trim the claims data of 10 all-inclusive rate providers reported in the December 2015 update of the FY 2015 MedPAR file, as well as any Medicare Advantage claims data for cases that would meet the criteria for exclusion from the site neutral payment rate under § 412.522(b) if the dual rate LTCH PPS payment structure were in effect at the time of discharge. (We note that there were no data from any LTCHs that are paid in accordance with a demonstration project reported in the December 2015 update of the FY 2015 MedPAR file. However, had there been we would trim the claims data from those LTCHs as well, in accordance with our established policy.) We would use the remaining data (that is, the applicable LTCH data) to calculate the proposed relative weights for FY 2017.

d. Hospital-Specific Relative Value (HSRV) Methodology

By nature, LTCHs often specialize in certain areas, such as ventilator-dependent patients. Some case types (MS–LTC–DRGs) may be treated, to a large extent, in hospitals that have, from a perspective of charges, relatively high (or low) charges. This nonrandom distribution of cases with relatively high (or low) charges in specific MS–LTC–DRGs has the potential to inappropriately distort the measure of average charges. To account for the fact that cases may not be randomly distributed across LTCHs, consistent with the methodology we have used since the implementation of the LTCH PPS, we are proposing to continue to use a hospital-specific relative value (HSRV) methodology to calculate the proposed MS–LTC–DRG relative weights for FY 2017. We believe that this method removes this hospital-specific source of bias in measuring LTCH average charges (67 FR 55985). Specifically, under this methodology, we are reducing the impact of the variation in charges across providers on any particular MS–LTC–DRG relative weight by converting each LTCH's charge for an applicable LTCH case to a relative value based on that LTCH's average charge for such cases.

Under the HSRV methodology, we standardize charges for each LTCH by converting its charges for each applicable LTCH case to hospital-specific relative charge values and then adjusting those values for the LTCH's case-mix. The adjustment for case-mix is needed to rescale the hospital-specific relative charge values (which, by definition, average 1.0 for each LTCH). The average relative weight for a LTCH is its case-mix; therefore, it is reasonable to scale each LTCH's average relative charge value by its case-mix. In this way, each LTCH's relative charge value is adjusted by its case-mix to an average that reflects the complexity of the applicable LTCH cases it treats relative to the complexity of the applicable LTCH cases treated by all other LTCHs (the average LTCH PPS case-mix of all applicable LTCH cases across all LTCHs).

In accordance with our established methodology, for FY 2017, we are proposing to continue to standardize charges for each applicable LTCH case by first dividing the adjusted charge for the case (adjusted for SSOs under § 412.529 as described in section VII.C.3.g. (Step 3) of the preamble of this proposed rule) by the average adjusted charge for all applicable LTCH cases at the LTCH in which the case was treated. SSO cases are cases with a length of stay that is less than or equal to five-sixths the average length of stay of the MS–LTC–DRG (§ 412.529 and § 412.503). The average adjusted charge reflects the average intensity of the health care services delivered by a particular LTCH and the average cost level of that LTCH. The resulting ratio would be multiplied by that LTCH's case-mix index to determine the standardized charge for the case.

Multiplying the resulting ratio by the LTCH's case-mix index accounts for the fact that the same relative charges are given greater weight at a LTCH with higher average costs than they would at a LTCH with low average costs, which is needed to adjust each LTCH's relative charge value to reflect its case-mix relative to the average case-mix for all LTCHs. By standardizing charges in this manner, we count charges for a Medicare patient at a LTCH with high average charges as less resource intensive than they would be at a LTCH with low average charges. For example, a $10,000 charge for a case at a LTCH with an average adjusted charge of $17,500 reflects a higher level of relative resource use than a $10,000 charge for a case at a LTCH with the same case-mix, but an average adjusted charge of $35,000. We believe that the adjusted charge of an individual case more accurately reflects actual resource use for an individual LTCH because the variation in charges due to systematic differences in the markup of charges among LTCHs is taken into account.

e. Treatment of Severity Levels in Developing the Proposed MS–LTC–DRG Relative Weights

For purposes of determining the proposed MS–LTC–DRG relative weights, under our historical methodology, there are three different categories of MS–DRGs based on volume of cases within specific MS–LTC–DRGs: (1) MS–LTC–DRGs with at least 25 applicable LTCH cases in the data used to calculate the relative weight, which are each assigned a unique relative weight; (2) low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases that are grouped into quintiles (as described later in this section of the proposed rule) and assigned the relative weight of the quintile; and (3) no-volume MS–LTC–DRGs that are cross-walked to other MS–LTC–DRGs based on the clinical similarities and assigned the relative weight of the cross-walked MS–LTC–DRG (as described in greater detail below). For FY 2017, we are proposing to continue to use applicable LTCH cases to establish the same volume-based categories to calculate the proposed FY 2017 MS–LTC–DRG relative weights.

In determining the proposed FY 2017 MS–LTC–DRG relative weights, when necessary, we are proposing to make adjustments to account for nonmonotonicity, as discussed in greater detail later in Step 6 of section VII.C.3.g. of the preamble of this proposed rule. We refer readers to the discussion in the FY 2010 IPPS/RY 2010 LTCH PPS final rule for our rationale for including an adjustment for nonmonotonicity (74 FR 43953 through 43954).

f. Proposed Low-Volume MS–LTC–DRGs

In order to account for MS–LTC–DRGs with low-volume (that is, with fewer than 25 applicable LTCH cases), consistent with our existing methodology, we are proposing to continue to employ the quintile methodology for proposed low-volume MS–LTC–DRGs, such that we grouped the "low-volume MS–LTC–DRGs" (that is, proposed MS–LTC–DRGs that contained between 1 and 24 applicable LTCH cases into one of five categories (quintiles) based on average charges (67 FR 55984 through 55995; 72 FR 47283 through 47288; and 80 FR 49628). In cases where the initial assignment of a low-volume MS–LTC–DRG to a quintile resulted in nonmonotonicity within a base-DRG, we are proposing to make adjustments to the resulting low-volume

MS–LTC–DRGs to preserve monotonicity, as discussed in detail in section VII.C.3.g. (Step 6) of the preamble of this proposed rule.

In this proposed rule, based on the best available data (that is, the December 2015 update of the FY 2015 MedPAR files), we identified 259 proposed MS–LTC–DRGs that contained between 1 and 24 applicable LTCH cases. This list of proposed MS–LTC–DRGs was then divided into one of the 5 low-volume quintiles, each containing 51 proposed MS–LTC–DRGs (259/5 = 51, with a remainder of 4). We assigned the proposed low-volume MS–LTC–DRGs to specific low-volume quintiles by sorting the proposed low-volume MS–LTC–DRGs in ascending order by average charge in accordance with our established methodology. Based on the data available for the proposed rule, the number of proposed MS–LTC–DRGs with less than 25 applicable LTCH cases is not evenly divisible by 5. Therefore, we are proposing to employ our historical methodology for determining which of the low-volume quintiles contain the additional proposed low-volume MS–LTC–DRG. Specifically for this proposed rule, after organizing the proposed MS–LTC–DRGs by ascending order by average charge, we assigned the first 51st (1st through 51st) of proposed low-volume MS–LTC–DRGs (with the lowest average charge) into Quintile 1. The 51 proposed MS–LTC–DRGs with the highest average charge cases were assigned into Quintile 5. Because the average charge of the 52nd proposed low-volume MS–LTC–DRG in the sorted list was closer to the average charge of the 51st proposed low-volume MS–LTC–DRG (assigned to Quintile 1) than to the average charge of the 53rd proposed low-volume MS–LTC–DRG (assigned to Quintile 2), we assigned it to Quintile 1 (such that Quintile 1 contains 52 proposed low-volume MS–LTC–DRGs before any adjustments for nonmonotonicity, as discussed below). This results in 4 of the 5 proposed low-volume quintiles containing 52 proposed MS–LTC–DRGs (Quintiles 1, 2, 3 and 4) and one proposed low-volume quintile containing 51 proposed MS–LTC–DRGs (Quintile 5). Table 13A, listed in section VI. of the Addendum to this proposed rule and available via the Internet on the CMS Web site, lists the composition of the proposed low-volume quintiles for MS–LTC–DRGs for FY 2017.

In order to determine the proposed FY 2017 relative weights for the proposed low-volume MS–LTC–DRGs, we are proposing to use the five proposed low-volume quintiles described previously. We determined a proposed relative weight and (geometric) average length of stay for each of the five proposed low-volume quintiles using the methodology described in section VII.C.3.g. of the preamble of this proposed rule. We are proposing to assign the same proposed relative weight and average length of stay to each of the proposed low-volume MS–LTC–DRGs that make up an individual low-volume quintile. We note that, as this system is dynamic, it is possible that the number and specific type of MS–LTC–DRGs with a low-volume of applicable LTCH cases would vary in the future. Furthermore, we note that we continue to monitor the volume (that is, the number of applicable LTCH cases) in the low-volume quintiles to ensure that our quintile assignments used in determining the MS–LTC–DRG relative weights result in appropriate payment for LTCH cases grouped to low-volume MS–LTC–DRGs and do not result in an unintended financial incentive for LTCHs to inappropriately admit these types of cases.

g. Steps for Determining the Proposed FY 2017 MS–LTC–DRG Relative Weights

In this proposed rule, we are proposing to continue to use our current methodology to determine the proposed FY 2017 MS–LTC–DRG relative weights.

In summary, to determine the proposed FY 2017 MS–LTC–DRG relative weights, we are proposing to group applicable LTCH cases to the appropriate proposed MS–LTC–DRG, while taking into account the proposed low-volume quintiles (as described above) and proposed cross-walked no-volume MS–LTC–DRGs (as described later in this section). After establishing the appropriate proposed MS–LTC–DRG (or proposed low-volume quintile), we calculate the proposed FY 2017 relative weights by first removing cases with a length of stay of 7 days or less and statistical outliers (Steps 1 and 2 below). Next, we adjust the number of applicable LTCH cases in each proposed MS–LTC–DRG (or proposed low-volume quintile) for the effect of SSO cases (Step 3 below). After removing applicable LTCH cases with a length of stay of 7 days or less (Step 1 below) and statistical outliers (Step 2 below), which are the SSO-adjusted applicable LTCH cases and corresponding charges (step 3 below), we calculate "relative adjusted weights" for each proposed MS–LTC–DRG (or low-volume quintile) using the HSRV method.

Step 1—Remove cases with a length of stay of 7 days or less.

The first step in our calculation of the proposed FY 2017 MS–LTC–DRG relative weights would be to remove cases with a length of stay of 7 days or less. The MS–LTC–DRG relative weights reflect the average of resources used on representative cases of a specific type. Generally, cases with a length of stay of 7 days or less do not belong in a LTCH because these stays do not fully receive or benefit from treatment that is typical in a LTCH stay, and full resources are often not used in the earlier stages of admission to a LTCH. If we were to include stays of 7 days or less in the computation of the proposed FY 2017 MS–LTC–DRG relative weights, the value of many relative weights would decrease and, therefore, payments would decrease to a level that may no longer be appropriate. We do not believe that it would be appropriate to compromise the integrity of the payment determination for those LTCH cases that actually benefit from and receive a full course of treatment at a LTCH by including data from these very short stays. Therefore, consistent with our existing relative weight methodology, in determining the proposed FY 2017 MS–LTC–DRG relative weights, we are proposing to remove LTCH cases with a length of stay of 7 days or less from applicable LTCH cases. (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 2—Remove statistical outliers.

The next step in our calculation of the proposed FY 2017 MS–LTC–DRG relative weights would be to remove statistical outlier cases from the LTCH cases with a length of stay of at least 8 days. Consistent with our existing relative weight methodology, we are proposing to continue to define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each MS–LTC–DRG. These statistical outliers are removed prior to calculating the relative weights because we believe that they may represent aberrations in the data that distort the measure of average resource use. Including those LTCH cases in the calculation of the relative weights could result in an inaccurate relative weight that does not truly reflect relative resource use among those MS–LTC–DRGs. (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.) After removing cases with a length of stay of 7 days or less and statistical outliers, we are left with applicable LTCH cases that have a length of stay greater than or equal to 8 days. In this proposed rule, we refer to these cases as "trimmed applicable LTCH cases."

Step 3—Adjust charges for the effects of SSOs.

As the next step in the calculation of the proposed FY 2017 MS–LTC–DRG relative weights, consistent with our historical approach, we are proposing to adjust each LTCH's charges per discharge for those remaining cases (that is, trimmed applicable LTCH cases) for the effects of SSOs (as defined in § 412.529(a) in conjunction with § 412.503). Specifically, we are proposing to make this adjustment by counting an SSO case as a fraction of a discharge based on the ratio of the length of stay of the case to the average length of stay for the MS–LTC–DRG for non-SSO cases. This has the effect of proportionately reducing the impact of the lower charges for the SSO cases in calculating the average charge for the MS–LTC–DRG. This process produces the same result as if the actual charges per discharge of an SSO case were adjusted to what they would have been had the patient's length of stay been equal to the average length of stay of the MS–LTC–DRG.

Counting SSO cases as full LTCH cases with no adjustment in determining the proposed FY 2017 MS–LTC–DRG relative weights would lower the proposed FY 2017 MS–LTC–DRG relative weight for affected proposed MS–LTC–DRGs because the relatively lower charges of the SSO cases would bring down the average charge for all cases within a proposed MS–LTC–DRG. This would result in an "underpayment" for non-SSO cases and an "overpayment" for SSO cases. Therefore, we are proposing to continue to adjust for SSO cases under § 412.529 in this manner because it would results in more appropriate payments for all LTCH PPS standard Federal payment rate cases. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 4—Calculate the proposed FY 2017 MS–LTC–DRG relative weights on an iterative basis.

Consistent with our historical relative weight methodology, we are proposing to calculate the proposed FY 2017 MS–LTC–DRG relative weights using the HSRV methodology, which is an iterative process. First, for each SSO-adjusted trimmed applicable LTCH case, we would calculate a hospital-specific relative charge value by dividing the charge per discharge after adjusting for SSOs of the LTCH case (from Step 3) by the average charge per SSO-adjusted discharge for the LTCH in which the case occurred. The resulting ratio was then would be multiplied by the LTCH's case-mix index to produce an adjusted hospital-specific relative charge value for the case. We use an initial case-mix index value of 1.0 for each LTCH.

For each proposed MS–LTC–DRG, we would calculate the proposed FY 2017 relative weight by dividing the SSO-adjusted average of the hospital-specific relative charge values for applicable LTCH cases for the proposed MS–LTC–DRG (that is, the sum of the hospital-specific relative charge value from above divided by the sum of equivalent cases from Step 3 for each proposed MS–LTC–DRG) by the overall SSO-adjusted average hospital-specific relative charge value across all applicable LTCH cases for all LTCHs (that is, the sum of the hospital-specific relative charge value from above divided by the sum of equivalent applicable LTCH cases from Step 3 for each proposed MS–LTC–DRG). Using these recalculated MS–LTC–DRG relative weights, each LTCH's average relative weight for all of its SSO-adjusted trimmed applicable LTCH cases (that is, its case-mix) would be calculated by dividing the sum of all the LTCH's MS–LTC–DRG relative weights by its total number of SSO-adjusted trimmed applicable LTCH cases. The LTCHs' hospital-specific relative charge values (from previous) were then multiplied by the hospital-specific case-mix indexes. The hospital-specific case-mix adjusted relative charge values would then be used to calculate a new set of MS–LTC–DRG relative weights across all LTCHs. This iterative process continues until there is convergence between the relative weights produced at adjacent steps, for example, when the maximum difference was less than 0.0001.

Step 5—Determine a proposed FY 2017 relative weight for MS–LTC–DRGs with no applicable LTCH cases.

Using the trimmed applicable LTCH cases, we are proposing to identify the proposed MS–LTC–DRGs for which there were no claims in the December 2015 update of the FY 2015 MedPAR file and, therefore, for which no charge data was available for these proposed MS–LTC–DRGs. Because patients with a number of the diagnoses under those proposed MS–LTC–DRGs may be treated at LTCHs, consistent with our historical methodology, we would generally assign a proposed relative weight to each of the no-volume proposed MS–LTC–DRGs based on clinical similarity and relative costliness (with the exception of "transplant" proposed MS–LTC–DRGs, "error" proposed MS–LTC–DRGs, and proposed MS–LTC–DRGs that indicate a principal diagnosis related to a psychiatric diagnosis or rehabilitation (referred to as the "psychiatric or rehabilitation" MS–LTC–DRGs), as discussed later in this section of the proposed rule). (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55991 and 74 FR 43959 through 43960.)

We are proposing to cross-walk each no-volume proposed MS–LTC–DRG to another proposed MS–LTC–DRG for which we would calculate a proposed relative weight (determined in accordance with the methodology described above). Then, the "no-volume" proposed MS–LTC–DRG would be assigned the same proposed relative weight (and average length of stay) of the proposed MS–LTC–DRG to which it was cross-walked (as described in greater detail in this section of the proposed rule).

Of the 757 proposed MS–LTC–DRGs for FY 2017, we identified 358 proposed MS–LTC–DRGs for which there are no trimmed applicable LTCH cases (the number identified includes the 8 "transplant" proposed MS–LTC–DRGs, the 2 "error" proposed MS–LTC–DRGs, and the 15 "psychiatric or rehabilitation" proposed MS–LTC–DRGs, which are discussed below). We are proposing to assign proposed relative weights to each of the 333 no-volume proposed MS–LTC–DRGs that contained trimmed applicable LTCH cases based on clinical similarity and relative costliness to one of the remaining 399 (757 − 358 = 399) proposed MS–LTC–DRGs for which we would calculate proposed relative weights based on the trimmed applicable LTCH cases in the FY 2015 MedPAR file data using the steps described previously. (For the remainder of this discussion, we refer to the "cross-walked" proposed MS–LTC–DRGs as the proposed MS–LTC–DRGs to which we cross-walked one of the 333 "no volume" proposed MS–LTC–DRGs.) Then, we generally assigned the 333 no-volume proposed MS–LTC–DRG the proposed relative weight of the cross-walked proposed MS–LTC–DRG. (As explained below in Step 6, when necessary, we made adjustments to account for nonmonotonicity.)

We are proposing to cross-walk the no-volume proposed MS–LTC–DRG to a proposed MS–LTC–DRG for which we would calculate proposed relative weights based on the December 2015 update of the FY 2015 MedPAR file, and to which it is similar clinically in intensity of use of resources and relative costliness as determined by criteria such as care provided during the period of time surrounding surgery, surgical approach (if applicable), length of time of surgical procedure, postoperative care, and length of stay. (For more details on our process for evaluating relative costliness, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (73 FR 48543).) We believe in the rare event that there would be a few LTCH cases grouped to one of the no-volume proposed MS–LTC–DRGs in FY 2017, the proposed relative weights assigned based on the cross-walked MS–LTC–DRGs would result in an appropriate LTCH PPS payment because the crosswalks, which are based on clinical similarity and relative costliness, would be expected to generally require equivalent relative resource use.

We are proposing to then assign the proposed relative weight of the cross-walked proposed MS–LTC–DRG as the proposed relative weight for the no-volume proposed MS–LTC–DRG such that both of these proposed MS–LTC–DRGs (that is, the no-volume proposed MS–LTC–DRG and the cross-walked proposed MS–LTC–DRG) have the same proposed relative weight (and average length of stay) for FY 2017. We note that, if the cross-walked proposed MS–LTC–DRG had 25 applicable LTCH cases or more, its proposed relative weight (calculated using the methodology described in Steps 1 through 4 above) was assigned to the no-volume proposed MS–LTC–DRG as well. Similarly, if the proposed MS–LTC–DRG to which the no-volume proposed MS–LTC–DRG was cross-walked had 24 or less cases and, therefore, was designated to one of the proposed low-volume quintiles for purposes of determining the proposed relative weights, we assigned the proposed relative weight of the applicable proposed low-volume quintile to the no-volume proposed MS–LTC–DRG such that both of these proposed MS–LTC–DRGs (that is, the no-volume proposed MS–LTC–DRG and the proposed cross-walked MS–LTC–DRG) have the same proposed relative weight for FY 2017. (As we noted previously, in the infrequent case where nonmonotonicity involving a no-volume proposed MS–LTC–DRG resulted, additional adjustments as described in Step 6 are required in order to maintain monotonically increasing relative weights.)

For this proposed rule, a list of the no-volume proposed MS–LTC–DRGs and the proposed MS–LTC–DRGs to which each would cross-walk (that is, the cross-walked proposed MS–LTC–DRGs) for FY 2017 is shown in Table 13B, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet on the CMS Web site.

To illustrate this methodology for determining the proposed relative weights for the FY 2017 proposed MS–LTC–DRGs with no applicable LTCH cases, we are providing the following example, which refers to the no-volume proposed MS–LTC–DRGs crosswalk information for FY 2017 provided in Table 13B.

Example: There were no trimmed applicable LTCH cases in the FY 2015 MedPAR file that we are using for this proposed rule for proposed MS–LTC–DRG 61 (Acute Ischemic Stroke with Use of Thrombolytic Agent with MCC). We determined that proposed MS–LTC–DRG 70 (Nonspecific Cerebrovascular Disorders with MCC) is similar clinically and based on resource use to proposed MS–LTC–DRG 61. Therefore, we assigned the same proposed relative weight (and average length of stay) of proposed MS–LTC–DRG 70 of 0.9156 for FY 2017 to proposed MS–LTC–DRG 61 (refer to Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the Internet on the CMS Web site).

Again, we note that, as this system is dynamic, it is entirely possible that the number of MS–LTC–DRGs with no volume would vary in the future. Consistent with our historical practice, we used the most recent available claims data to identify the trimmed applicable LTCH cases from which we determined the proposed relative weights in this proposed rule.

For FY 2017, consistent with our historical relative weight methodology, we are proposing to establish a relative weight of 0.0000 for the following transplant proposed MS–LTC–DRGs: Heart Transplant or Implant of Heart Assist System with MCC (MS–LTC–DRG 1); Heart Transplant or Implant of Heart Assist System without MCC (MS–LTC–DRG 2); Liver Transplant with MCC or Intestinal Transplant (MS–LTC–DRG 5); Liver Transplant without MCC (MS–LTC–DRG 6); Lung Transplant (MS–LTC–DRG 7); Simultaneous Pancreas/Kidney Transplant (MS–LTC–DRG 8); Pancreas Transplant (MS–LTC–DRG 10); and Kidney Transplant (MS–LTC–DRG 652). This is because Medicare only covers these procedures if they are performed at a hospital that has been certified for the specific procedures by Medicare and presently no LTCH has been so certified. At the present time, we include these eight transplant proposed MS–LTC–DRGs in the GROUPER program for administrative purposes only. Because we use the same GROUPER program for LTCHs as is used under the IPPS, removing these proposed MS–LTC–DRGs would be administratively burdensome. (For additional information regarding our treatment of transplant MS–LTC–DRGs, we refer readers to the RY 2010 LTCH PPS final rule (74 FR 43964).) In addition, consistent with our historical policy and we are proposing to establish a relative weight of 0.0000 for the 2 "error" proposed MS–LTC–DRGs (that is, MS–LTC–DRG 998 (Principal Diagnosis Invalid as Discharge Diagnosis) and MS–LTC–DRG 999 (Ungroupable)) because applicable LTCH cases grouped to these proposed MS–LTC–DRGs cannot be properly assigned to an MS–LTC–DRG according to the grouping logic.

In this proposed rule, for FY 2017, we are proposing to establish a proposed relative weight equal to the respective FY 2015 relative weight of the MS–LTC–DRGs for the following "psychiatric or rehabilitation" proposed MS–LTC–DRGs: MS–LTC–DRG 876 (O.R. Procedure with Principal Diagnoses of Mental Illness); MS–LTC–DRG 880 (Acute Adjustment Reaction & Psychosocial Dysfunction); MS–LTC–DRG 881 (Depressive Neuroses); MS–LTC–DRG 882 (Neuroses Except Depressive); MS–LTC–DRG 883 (Disorders of Personality & Impulse Control); MS–LTC–DRG 884 (Organic Disturbances & Mental Retardation); MS–LTC–DRG 885 (Psychoses); MS–LTC–DRG 886 (Behavioral & Developmental Disorders); MS–LTC–DRG 887 (Other Mental Disorder Diagnoses); MS–LTC–DRG 894 (Alcohol/Drug Abuse or Dependence, Left Ama); MS–LTC–DRG 895 (Alcohol/Drug Abuse or Dependence, with Rehabilitation Therapy); MS–LTC–DRG 896 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy with MCC); MS–LTC–DRG 897 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy without MCC); MS–LTC–DRG 945 (Rehabilitation with CC/MCC); and MS–LTC–DRG 946 (Rehabilitation without CC/MCC). As we discussed when we implemented the dual rate LTCH PPS payment structure, LTCH discharges that are grouped to these 15 "psychiatric and rehabilitation" MS–LTC–DRGs do not meet the criteria for exclusion from the site neutral payment rate. As such, under the criterion for a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation, there are no applicable LTCH cases to use in calculating a relative weight for the "psychiatric and rehabilitation" proposed MS–LTC–DRGs. In other words, any LTCH PPS discharges grouped to any of the 15 "psychiatric and rehabilitation" proposed MS–LTC–DRGs will always be paid at the site neutral payment rate, and, therefore, those proposed MS–LTC–DRGs will never include any LTCH cases that meet the criteria for exclusion from the site neutral payment rate. However, section 1886(m)(6)(B) of the Act establishes a transitional payment method for cases that would be paid at the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 or FY 2017. Under the transitional payment method for site neutral payment rate cases, for LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2016, and on or before September 30, 2017, site neutral payment rate cases are paid a blended payment rate, calculated as 50 percent of the applicable site neutral payment rate amount for the discharge and 50 percent of the applicable LTCH PPS standard Federal payment rate. Because the LTCH PPS standard Federal payment rate is based on the relative weight of the MS–LTC–DRG, in order to determine the transitional blended payment for site neutral payment rate cases grouped to one of the "psychiatric or rehabilitation" proposed MS–LTC–DRGs in FY 2017, we are proposing to assign a proposed relative weight to these proposed MS–LTC–DRGs for FY 2017, that would be the same as the FY 2015 relative weight (which is also the same as the FY 2016 relative weight). We believe that using the respective FY 2015 relative weight for each of the "psychiatric or rehabilitation" proposed MS–LTC–DRGs results in appropriate payments for LTCH cases that are paid at the site neutral payment rate under the transition policy provided by the statute because there are no clinically similar MS–LTC–DRGs for which we were able to determine relative weights based on applicable LTCH cases in the FY 2015 MedPAR file data using the steps described above. Furthermore, we believe that it would be administratively burdensome and introduce unnecessary complexity to the MS–LTC–DRG relative weight calculation to use the LTCH discharges in the MedPAR file data to calculate a relative weight for those 15 "psychiatric and rehabilitation" proposed MS–LTC–DRGs to be used for the sole purpose of determining half of the transitional blended payment for site neutral payment rate cases during the transition period. (80 FR 49631 through 49632)

In summary, for FY 2017, we are proposing to establish a proposed relative weight (and average length of stay thresholds) equal to the respective FY 2015 relative weight of the proposed MS–LTC–DRGs for the 15 "psychiatric or rehabilitation" proposed MS–LTC–DRGs listed previously (that is, MS–LTC–DRGs 876, 880, 881, 882, 883, 884, 885, 886, 887, 894, 895, 896, 897, 945, and 946). Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet on the CMS Web site, reflects this proposal.

Step 6—Adjust the proposed FY 2017 MS–LTC–DRG relative weights to account for nonmonotonically increasing relative weights.

The MS–DRGs contain base DRGs that have been subdivided into one, two, or three severity of illness levels. Where there are three severity levels, the most severe level has at least one secondary diagnosis code that is referred to as an MCC (that is, major complication or comorbidity). The next lower severity level contains cases with at least one secondary diagnosis code that is a CC (that is, complication or comorbidity). Those cases without an MCC or a CC are referred to as "without CC/MCC." When data do not support the creation of three severity levels, the base MS–DRG is subdivided into either two levels or the base MS–DRG is not subdivided. The two-level subdivisions could consist of the MS–DRG with CC/MCC and the MS–DRG without CC/MCC. Alternatively, the other type of two-level subdivision may consist of the MS–DRG with MCC and the MS–DRG without MCC.

In those base MS–LTC–DRGs that are split into either two or three severity levels, cases classified into the "without CC/MCC" MS–LTC–DRG are expected to have a lower resource use (and lower costs) than the "with CC/MCC" MS–LTC–DRG (in the case of a two-level split) or both the "with CC" and the "with MCC" MS–LTC–DRGs (in the case of a three-level split). That is, theoretically, cases that are more severe typically require greater expenditure of medical care resources and would result in higher average charges. Therefore, in the three severity levels, relative weights should increase by severity, from lowest to highest. If the relative weights decrease as severity increases (that is, if within a base MS–LTC–DRG, an MS–LTC–DRG with CC has a higher relative weight than one with MCC, or the MS–LTC–DRG "without CC/MCC" has a higher relative weight than either of the others), they are nonmonotonic. We continue to believe that utilizing nonmonotonic relative weights to adjust Medicare payments would result in inappropriate payments because the payment for the cases in the higher severity level in a base MS–LTC–DRG (which are generally expected to have higher resource use and costs) would be lower than the payment for cases in a lower severity level within the same base MS–LTC–DRG (which are generally expected to have lower resource use and costs). Therefore, in determining the proposed FY 2017 MS–LTC–DRG relative weights, consistent with our historical methodology, we are proposing to continue to combine MS–LTC–DRG severity levels within a base MS–LTC–DRG for the purpose of computing a proposed relative weight when necessary to ensure that monotonicity is maintained. For a comprehensive description of our existing methodology to adjust for nonmonotonicity, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43964 through 43966). Any adjustments for nonmonotonicity that were made in determining the proposed FY 2017 MS–LTC–DRG relative weights in this proposed rule by applying this methodology are denoted in Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet on the CMS Web site.

Step 7—Calculate the proposed FY 2017 MS–LTC–DRG reclassification and recalibration budget neutrality factor.

In accordance with the regulations at § 412.517(b) (in conjunction with § 412.503), the annual update to the MS–LTC–DRG classifications and relative weights is done in a budget neutral manner such that estimated aggregate LTCH PPS payments would be unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without the MS–LTC–DRG classification and relative weight changes. (For a detailed discussion on the establishment of the budget neutrality requirement for the annual update of the MS–LTC–DRG classifications and relative weights, we refer readers to the RY 2008 LTCH PPS final rule (72 FR 26881 and 26882).)

The MS–LTC–DRG classifications and relative weights are updated annually based on the most recent available LTCH claims data to reflect changes in relative LTCH resource use (§ 412.517(a) in conjunction with § 412.503). To achieve the budget neutrality requirement at § 412.517(b), under our established methodology, for each annual update, the MS–LTC–DRG relative weights are uniformly adjusted to ensure that estimated aggregate payments under the LTCH PPS would not be affected (that is, decreased or increased). Consistent with that provision, we are proposing to update the MS–LTC–DRG classifications and relative weights for FY 2017 based on the most recent available LTCH data for applicable LTCH cases, and to continue to apply a budget neutrality adjustment in determining the FY 2017 MS–LTC–DRG relative weights.

To ensure budget neutrality in the update to the MS–LTC–DRG classifications and relative weights under § 412.517(b), we are proposing to continuing to use our established two-step budget neutrality methodology. Therefore, in this proposed rule, in the first step of our MS–LTC–DRG budget neutrality methodology, for FY 2017, we are proposing to calculate and apply a normalization factor to the recalibrated relative weights (the result of Steps 1 through 6 discussed previously) to ensure that estimated payments are not affected by changes in the composition of case types or the changes to the classification system. That is, the proposed normalization adjustment is intended to ensure that the recalibration of the MS–LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average case-mix index.

To calculate the proposed normalization factor for FY 2017 (the first step of our budget neutrality methodology), we used the following three steps: (1.a.) Use the most recent available applicable LTCH cases from the most recent available data (that is, LTCH discharges from the FY 2015 MedPAR file) and grouped them using the proposed FY 2017 GROUPER (that is, proposed Version 34 for FY 2017) and the recalibrated FY 2017 MS–LTC–DRG relative weights (determined in Steps 1 through 6 above) to calculate the average case-mix index; (1.b.) group the same applicable LTCH cases (as are used in Step 1.a.) using the FY 2016 GROUPER (Version 33) and FY 2016 MS–LTC–DRG relative weights and calculated the average case-mix index; and (1.c.) compute the ratio of these average case-mix indexes by dividing the average CMI for FY 2016 (determined in Step 1.b.) by the average case-mix index for FY 2017 (determined in Step 1.a.). As a result, in determining the proposed MS–LTC–DRG relative weights for FY 2017, each recalibrated MS–LTC–DRG relative weight is multiplied by the proposed normalization factor of 1.28094 (determined in Step 1.c.) in the first step of the budget neutrality methodology, which produces "normalized relative weights."

In the second step of our MS–LTC–DRG budget neutrality methodology, we are proposing to calculate a second budget neutrality factor consisting of the ratio of estimated aggregate FY 2017 LTCH PPS standard Federal payment rate payments for applicable LTCH cases (the sum of all calculations under Step 1.a. mentioned previously) after reclassification and recalibration to estimated aggregate payments for FY 2017 LTCH PPS standard Federal payment rate payments for applicable LTCH cases before reclassification and recalibration (that is, the sum of all calculations under Step 1.b. mentioned previously).

That is, for this proposed rule, for FY 2017, under the second step of the budget neutrality methodology, we determined the budget neutrality adjustment factor using the following three steps: (2.a.) Simulate estimated total FY 2017 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the normalized relative weights for FY 2017 and proposed GROUPER Version 34 (as described above); (2.b.) simulate estimated total FY 2016 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2016 GROUPER (Version 33) and the FY 2016 MS–LTC–DRG relative weights in Table 11 of the FY 2016 IPPS/LTCH PPS final rule available on the Internet, as described in section VI. of the Addendum of that final rule; and (2.c.) calculate the ratio of these estimated total payments by dividing the value determined in Step 2.b. by the value determined in Step 2.a. In determining the proposed FY 2017 MS–LTC–DRG relative weights, each proposed normalized relative weight was then multiplied by a proposed budget neutrality factor of 0.998723 (the value determined in Step 2.c.) in the second step of the budget neutrality methodology to achieve the budget neutrality requirement at § 412.517(b).

Accordingly, in determining the proposed FY 2017 MS–LTC–DRG relative weights in this proposed rule, consistent with our existing methodology, we are proposing to apply a proposed normalization factor of 1.28094 and a proposed budget neutrality factor of 0.998723. Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet on the CMS Web site, lists the proposed MS–LTC–DRGs and their respective proposed relative weights, geometric mean length of stay, five-sixths of the geometric mean length of stay (used to identify SSO cases under § 412.529(a)), and the "IPPS Comparable Thresholds" (used in determining SSO payments under § 412.529(c)(3)), for FY 2017.

D. Proposed Rebasing of the LTCH Market Basket

1. Background

The input price index (that is, the market basket) that was used to develop the LTCH PPS for FY 2003 was the "excluded hospital with capital" market basket. That market basket was based on 1997 Medicare cost report data and included data for Medicare-participating IRFs, IPFs, LTCHs, cancer hospitals, and children's hospitals. Although the term "market basket" technically describes the mix of goods and services used in providing hospital care, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies combined) derived from that mix. Accordingly, the term "market basket," as used in this section, refers to an input price index.

Beginning with RY 2007, LTCH PPS payments were updated using a 2002-based market basket reflecting the operating and capital cost structures for IRFs, IPFs, and LTCHs (hereafter referred to as the rehabilitation, psychiatric, and long-term care (RPL) market basket). We excluded cancer and children's hospitals from the RPL market basket because their payments are based entirely on reasonable costs subject to rate-of-increase limits established under the authority of section 1886(b) of the Act, which are implemented in regulations at 42 CFR 413.40. Those types of hospitals are not paid under a PPS. Also, the 2002 cost structures for cancer and children's hospitals are noticeably different from the cost structures for freestanding IRFs, freestanding IPFs, and LTCHs. A complete discussion of the 2002-based RPL market basket can be found in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817).

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51756), we finalized the rebasing and revising of the 2002-based RPL market basket by creating and implementing a 2008-based RPL market basket. We also discussed the creation of a stand-alone LTCH market basket and received several public comments, all of which supported deriving a stand-alone LTCH market basket (76 FR 51756 through 51757). In the FY 2013 IPPS/LTCH PPS final rule, we finalized the adoption of a stand-alone 2009-based LTCH-specific market basket that reflects the cost structures of LTCHs only (77 FR 53467 through 53479).

For this FY 2017 proposed rule, we are proposing to rebase and revise the 2009-based LTCH-specific market basket. The proposed LTCH market basket is primarily based on Medicare cost report data for LTCHs for 2013, which are for cost reporting periods beginning on and after October 1, 2012, and before October 1, 2013. We are proposing to use data from cost reports beginning in FY 2013 because these data are the latest available complete data for purposes of calculating cost weights for the market basket. In the following discussion, we provide an overview of the proposed LTCH market basket and describe the methodologies we are proposing to use for determining the operating and capital portions of the proposed 2013-based LTCH market basket.

2. Overview of the Proposed 2013-Based LTCH Market Basket

Similar to the 2009-based LTCH-specific market basket, the proposed 2013-based LTCH market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix (that is, intensity) of goods and services purchased over time are not measured.

The index itself is constructed using three steps. First, a base period is selected (in this proposed rule, we are proposing to use 2013 as the base period) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories, with the proportion of total costs that each category represents being calculated. These proportions are called "cost weights" or "expenditure weights." Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a "price proxy." In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As noted above, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to furnish hospital services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, a hospital hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the hospital, but would not be factored into the price change measured by a fixed-weight hospital market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect a recent mix of goods and services that hospitals purchase (hospital inputs) to furnish inpatient care.

3. Development of the Proposed 2013-Based LTCH Market Basket Cost Categories and Weights

We are inviting public comments on our proposed methodology, discussed below, for deriving the proposed 2013-based LTCH market basket.

a. Use of Medicare Cost Report Data

The proposed 2013-based LTCH market basket consists of six major cost categories derived from the 2013 LTCH Medicare cost reports (CMS Form 2552–10), including wages and salaries, employee benefits, contract labor, pharmaceuticals, professional liability insurance, and capital. After we calculate these cost categories, we are left with a residual cost category, which reflects all other input costs other than those captured in the six cost categories above. This is the same number of cost categories derived for the 2009-based LTCH-specific market basket using the 2009 Medicare cost report data (CMS Form 2552–96). These 2013 Medicare cost reports include data for cost reporting periods beginning on and after October 1, 2012, and before October 1, 2013. We are proposing to use 2013 as the base year because we believe that the 2013 Medicare cost reports represent the most recent, complete set of Medicare cost report data available to develop cost weights for an LTCH market basket. Medicare cost report data include costs for all patients, including Medicare, Medicaid, and private payer.

Because our goal is to measure cost shares for facilities that serve Medicare beneficiaries, and are reflective of case-mix and practice patterns associated with providing services to Medicare beneficiaries in LTCHs, we are proposing to limit our selection of Medicare cost reports to those from LTCHs that have a Medicare average length of stay (LOS) that is within a comparable range of their total facility average LOS. We define the Medicare average LOS based on data reported on the Medicare cost report (CMS Form 2552–10) Worksheet S–3, Part I, Line 14. We believe that applying the LOS edit results in a more accurate reflection of the structure of costs for Medicare covered days. For the 2009-based LTCH-specific market basket, we used the cost reports submitted by LTCHs with Medicare average LOS within 15 percent (that is, 15 percent higher or lower) of the total facility average LOS for the hospital.

Based on our analysis of the 2013 Medicare cost reports, for the proposed 2013-based LTCH market basket, we are proposing to use the cost reports submitted by LTCHs with Medicare average LOS within 25 percent (that is, 25 percent higher or lower) of the total facility average LOS for the hospital (this edit excludes 6 percent of LTCH providers). Applying the proposed trim results in a subset of LTCH Medicare cost reports with an average Medicare LOS of 27 days, average facility LOS of 28 days, and aggregate Medicare utilization (as measured by Medicare inpatient LTCH days as a percentage of total facility inpatient LTCH days) of 66 percent. If we were to apply the same trim as was applied for the 2009-based LTCH-specific market basket, we would exclude 11 percent of LTCH providers, but the results would be very similar with an average Medicare LOS of 27 days, average facility LOS of 27 days, and aggregate Medicare utilization of 66 percent. The 6 percent of providers that are excluded from the proposed 2013-based LTCH market basket have an average Medicare LOS of 29 days, average facility LOS of 77 days, and aggregate Medicare utilization of 12 percent. We believe that the use of this proposed trim, instead of the trim used to develop the 2009-based LTCH-specific market basket, is a technical improvement because data from more LTCHs are used while still being reflective of case-mix and practice patterns associated with providing services to Medicare beneficiaries.

Using the resulting set of Medicare cost reports, we are proposing to calculate cost weights for seven major cost categories of the proposed 2013-based LTCH market basket (wages and salaries, employee benefits, contract labor, professional liability insurance, pharmaceuticals, capital, and an "all other" residual cost category). The methodology used to develop the proposed 2013-based LTCH market basket cost weights is generally the same methodology used to develop the 2009-based LTCH-specific market basket cost weights. We describe the detailed methodology for obtaining costs for each of these seven cost categories below.

(1) Wages and Salaries Costs

We are proposing to derive wages and salaries costs as the sum of inpatient salaries, ancillary salaries, and a proportion of overhead (or general service cost center) salaries as reported on Worksheet A, Column 1. Because overhead salary costs are attributable to the entire LTCH, we are proposing to only include the proportion attributable to the Medicare allowable cost centers. Similar to the 2009-based LTCH-specific market basket major cost weights, we define Medicare allowable total costs (routine, ancillary and capital) as costs that are eligible for payment through the LTCH PPS. We are proposing to estimate the proportion of overhead salaries that are attributed to Medicare allowable costs centers by multiplying the ratio of Medicare allowable cost centers' salaries to total salaries (Worksheet A, Column 1, Line 200) by total overhead salaries. A similar methodology was used to derive wages and salaries costs in the 2009-based LTCH-specific market basket.

(2) Employee Benefit Costs

Similar to the 2009-based LTCH-specific market basket, we are proposing to calculate employee benefit costs using Worksheet S3, Part II. The completion of Worksheet S–3, Part II is only required for IPPS hospitals. However, for 2013, we found that roughly 35 percent of all LTCHs voluntarily reported these data (similar to prior years). We note that this worksheet is only required to be completed by IPPS hospitals. Our analysis of the Worksheet S–3, Part II data submitted by these LTCHs indicates that we had a large enough sample to enable us to produce a reasonable employee benefits cost weight. Specifically, we found that when we recalculated the cost weight after weighting to reflect the characteristics of the universe of LTCHs (type of control (nonprofit, for-profit, and government) and by region), the recalculation did not have a material effect on the resulting cost weight. Therefore, we are proposing to use Worksheet S–3, Part II data (as was done for the 2009-based LTCH-specific market basket) to calculate the employee benefit cost weight in the proposed 2013-based LTCH market basket.

We note that, effective with the implementation of CMS Form 2552–10 for cost reporting periods beginning on or after May 1, 2010, CMS began collecting employee benefits and contract labor data on Worksheet S–3, Part V, which is applicable to LTCHs. Only a few LTCHs reported these data and, therefore, we were unable to use such a small sample to accurately reflect these costs. Therefore, we encourage all LTCHs to report employee benefit and contract labor costs on Worksheet S–3, Part V.

(3) Contract Labor Costs

Contract labor costs are primarily associated with direct patient care services. Contract labor costs for services such as accounting, billing, and legal are estimated using other government data sources as described below. As was done for the 2009-based LTCH-specific market basket, we are proposing to derive the contract labor cost weight for the proposed 2013-based LTCH market basket using voluntarily reported data from Worksheet S–3, Part II. Approximately 48 percent of LTCHs voluntarily reported contract labor cost on the Worksheet S–3, Part II. Our analysis of these data indicates that we have a large enough sample to enable us to produce a reasonable contract labor cost weight. Specifically, we found that when we recalculated the cost weight after weighting to reflect the characteristics of the universe of LTCHs (type of control (nonprofit, for-profit, and government) and by region), the recalculation did not have a material effect on the resulting cost weight. Therefore, as was done for the 2009-based LTCH-specific market basket, we are proposing to use Worksheet S–3, Part II to calculate the contract labor cost weight in the proposed 2013-based LTCH market basket.

(4) Pharmaceutical Costs

We are proposing to calculate pharmaceutical costs using nonsalary costs reported on Worksheet A, Column 7, minus the amount on Worksheet A, Column 1, for the pharmacy cost center (Line 15) and drugs charged to patients cost center (Line 73). A similar methodology was used for the 2009-based LTCH-specific market basket using the CMS Form 2552–96.

(5) Professional Liability Insurance Costs

We are proposing that professional liability insurance (PLI) costs (often referred to as malpractice costs) be equal to premiums, paid losses and self-insurance costs reported on Worksheet S2, Part I, Line 118, Columns 1 through 3. A similar methodology was used for the 2009-based LTCH-specific market basket using the CMS Form 2552–96.

(6) Capital Costs

We are proposing that capital costs be equal to Medicare allowable capital costs as reported on Worksheet B, Part II, Column 26. We are proposing to define Medicare allowable costs as cost centers: 30 through 35, 50 through 76 (excluding 52, 61, and 75), 90 through 91 and 93. A similar methodology was used for the 2009-based LTCH-specific market basket using the CMS Form 2552–96.

b. Final Major Cost Category Computation

In addition to our proposals to derive costs for the major cost categories for each provider using the Medicare cost report data as previously described, we are proposing to address outlier cases using the following steps. First, for each provider, we are proposing to divide the costs for each of the six categories by the total Medicare allowable costs to obtain cost weights for the universe of LTCH providers. We are proposing to define total Medicare allowable costs reported on Worksheet B, Part I, Column 26 for cost centers: 30 Through 35, 50 through 76 (excluding 52, 61, and 75), 90 through 91 and 93.

We then are proposing to remove those providers whose derived cost weights fall in the top and bottom 5 percent of provider-specific derived cost weights to ensure the removal of costs for outlier cases. After the costs for outlier cases have been removed in this manner, we are proposing to sum the costs for each category across all remaining providers, and then divide this by the sum of total Medicare allowable costs across all remaining providers to obtain a cost weight for the proposed 2013-based LTCH market basket for the given category. Finally, we are proposing to calculate a seventh major cost weight—the residual "All Other" cost weight to reflect all remaining costs that are not captured in the previous six cost categories listed. We refer readers to Table VII–1 below for the resulting proposed cost weights for these major cost categories.

TABLE VII–1—MAJOR COST CATEGORIES AND THEIR RESPECTIVE COST WEIGHTS AS CALCULATED FROM MEDICARE COST REPORTS

Major cost categories	Proposed 2013-based LTCH market basket cost weight (percent of total costs)	2009-based LTCH-specific market basket cost weight (percent of total costs)
Wages and Salaries	41.5	40.4
Employee Benefits	6.5	7.0
Contract Labor	5.9	6.9
Professional Liability Insurance (Malpractice)	0.9	0.8
Pharmaceuticals	7.6	8.9
Capital	9.7	9.8
All Other	27.8	26.1

The wages and salaries cost weight calculated from the Medicare cost reports for the proposed 2013-based LTCH market basket is approximately 1 percentage point higher than the wages and salaries cost weight for the 2009-based LTCH-specific market basket, while the contract labor cost weight is approximately 1 percentage point lower. The proposed 2013-based pharmaceuticals cost weight also is roughly 1 percentage point lower than the cost weight for the 2009-based LTCH-specific market basket.

As we did for the 2009-based LTCH market basket, we are proposing to allocate the contract labor cost weight to the wages and salaries and employee benefits cost weights based on their relative proportions under the assumption that contract labor costs are comprised of both wages and salaries and employee benefits. The contract labor allocation proportion for wages and salaries is equal to the wages and salaries cost weight as a percent of the sum of the wages and salaries cost weight and the employee benefits cost weight. This rounded percentage is 86 percent. Therefore, we are proposing to allocate 86 percent of the contract labor cost weight to the wages and salaries cost weight and 14 percent to the employee benefits cost weight. We refer readers to Table VII–2 below that shows the proposed wages and salaries and employee benefit cost weights after contract labor cost weight allocation for both the proposed 2013-based LTCH market basket and the 2009-based LTCH-specific market basket.

TABLE VII–2—WAGES AND SALARIES AND EMPLOYEE BENEFITS COST WEIGHTS AFTER CONTRACT LABOR ALLOCATION

Major cost categories	Proposed 2013-based LTCH cost weight (percent of total costs)	2009-based LTCH-specific cost weight (percent of total costs)
Wages and Salaries	46.6	46.3
Employee Benefits	7.3	8.0
Compensation	53.9	54.3

After the allocation of the contract labor cost weight, the proposed 2013-based wages and salaries cost weight is 0.3 percentage point higher, while the employee benefit cost weight is 0.7 percentage point lower, relative to the respective cost weights for the 2009-based LTCH-specific market basket. As a result, in the proposed 2013-based LTCH market basket, the compensation cost weight is 0.4 percentage point lower than the compensation cost weight for the 2009-based LTCH-specific market basket.

c. Derivation of the Detailed Operating Cost Weights

To further divide the "All Other" residual cost weight estimated from the 2013 Medicare cost report data into more detailed cost categories, we are proposing to use the 2007 Benchmark Input-Output (I–O) "Use Tables/Before Redefinitions/Purchaser Value" for NAICS 622000, Hospitals, published by the Bureau of Economic Analysis (BEA). These data are publicly available at the following Web site: *http://www.bea.gov/industry/io_annual.htm.*

The BEA Benchmark I–O data are scheduled for publication every 5 years with the most recent data available for 2007. The 2007 Benchmark I–O data are derived from the 2007 Economic Census and are the building blocks for BEA's economic accounts. Therefore, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is produced and distributed.[72] BEA also produces Annual I–O estimates. However, while based on a similar methodology, these estimates reflect less comprehensive and less detailed data sources and are subject to revision when benchmark data becomes available. Instead of using the less detailed Annual I–O data, we are proposing to inflate the 2007 Benchmark I–O data forward to 2013 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2007 Benchmark I–O data. We repeated this practice for each year. We then calculated the cost shares that each cost category represents of the 2007 data inflated to 2013. These resulting 2013 cost shares were applied to the "All Other" residual cost weight to obtain the detailed cost weights for the proposed 2013-based LTCH market basket. For example, the cost for Food: Direct Purchases represents 6.5 percent of the sum of the "All Other" 2007 Benchmark I–O Hospital Expenditures inflated to 2013. Therefore, the Food: Direct Purchases cost weight represents

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[72] *http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.*

6.5 percent of the proposed 2013-based LTCH market basket's "All Other" cost category (27.8 percent), yielding a "final" Food: Direct Purchases proposed cost weight of 1.8 percent in the proposed 2013-based LTCH market basket (0.065 × 27.8 percent = 1.8 percent).

Using this methodology, we are proposing to derive 18 detailed LTCH market basket cost category weights from the proposed 2013-based LTCH market basket residual cost weight (27.8 percent). These categories are: (1) Electricity; (2) Fuel, Oil, and Gasoline; (3) Water and Sewerage; (4) Food: Direct Purchases; (5) Food: Contract Services; (6) Chemicals; (7) Medical Instruments; (8) Rubber and Plastics; (9) Paper and Printing Products; (10) Miscellaneous Products; (11) Professional Fees: Labor-Related; (12) Administrative and Facilities Support Services; (13) Installation, Maintenance, and Repair Services; (14) All Other Labor-Related Services; (15) Professional Fees: Nonlabor-Related; (16) Financial Services; (17) Telephone Services; and (18) All Other Nonlabor-Related Services.

d. Derivation of the Detailed Capital Cost Weights

As described in section VII.D.3.b. of the preamble of this proposed rule, we are proposing a capital-related cost weight of 9.7 percent as calculated from the 2013 Medicare cost reports for LTCHs after applying the proposed trims described above. We are proposing to then separate this total capital-related cost weight into more detailed cost categories.

Using 2013 Medicare cost reports, we are able to group capital-related costs into the following categories: Depreciation, Interest, Lease, and Other Capital-Related costs. For each of these categories, we are proposing to determine what proportion of total capital-related costs the category represents using the data reported by the LTCH on Worksheet A–7, which is the same methodology used for the 2009-based LTCH-specific market basket.

We also are proposing to allocate lease costs across each of the remaining detailed capital-related cost categories as was done in the 2009-based LTCH-specific market basket. This would result in three primary capital-related cost categories in the proposed 2013-based LTCH market basket: Depreciation, Interest, and Other Capital-Related costs. Lease costs are unique in that they are not broken out as a separate cost category in the proposed 2013-based LTCH market basket. Rather, we are proposing to proportionally distribute these costs among the cost categories of Depreciation, Interest, and Other Capital-Related, reflecting the assumption that the underlying cost structure of leases is similar to that of capital-related costs in general. As was done for the 2009-based LTCH-specific market basket, we are proposing to assume that 10 percent of the lease costs as a proportion of total capital-related costs (62.3 percent) represents overhead and to assign those costs to the Other Capital-Related cost category accordingly. Therefore, we are assuming that approximately 6.2 percent (62.3 percent × 0.1) of total capital-related costs represent lease costs attributable to overhead, and we are proposing to add this 6.2 percent to the 5.9 percent Other Capital-Related cost category weight. We are then proposing to distribute the remaining lease costs (56.1 percent, or 62.3 percent–6.2 percent) proportionally across the three cost categories (Depreciation, Interest, and Other Capital-Related) based on the proportion that these categories comprise of the sum of the Depreciation, Interest, and Other Capital-Related cost categories (excluding lease expenses). For example, the Other Capital-Related capital cost category represented 15.5 percent of all three cost categories (Depreciation, Interest, and Other Capital-Related) prior to any lease expenses being allocated. This 15.5 percent is applied to the 56.1 percent of remaining lease expenses so that another 8.7 percent of lease expenses as a percent of total capital-related costs is allocated to the Other Capital-Related cost category. Therefore, the resulting proposed Other Capital-Related cost weight is 20.8 percent (5.9 percent + 6.2 percent + 8.7 percent). This is the same methodology used for the 2009-based LTCH-specific market basket. The proposed allocation of these lease expenses are shown in Table VII–3.

Finally, we are proposing to further divide the Depreciation and Interest cost categories. We are proposing to separate Depreciation cost category into the following two categories: (1) Building and Fixed Equipment and (2) Movable Equipment. We also are proposing to separate the Interest cost category into the following two categories: (1) Government/Nonprofit; and (2) For-profit.

To disaggregate the depreciation cost weight, we needed to determine the percent of total depreciation costs for LTCHs (after the allocation of lease costs) that are attributable to building and fixed equipment, which we hereafter refer to as the "fixed percentage." We are proposing to use depreciation and lease data from Worksheet A–7 of the 2013 Medicare cost reports, which is the same methodology used for the 2009-based LTCH-specific market basket. Based on the 2013 LTCH Medicare cost report data, we have determined that depreciation costs for building and fixed equipment account for 39 percent of total depreciation costs, while depreciation costs for movable equipment account for 61 percent of total depreciation costs. As mentioned above, we are proposing to allocate lease expenses among the Depreciation, Interest, and Other Capital cost categories. We determined that leasing building and fixed equipment expenses account for 86 percent of total leasing expenses, while leasing movable equipment expenses account for 14 percent of total leasing expenses. We are proposing to sum the depreciation and leasing expenses for building and fixed equipment, as well as sum the depreciation and leasing expenses for movable equipment. This results in the proposed building and fixed equipment depreciation cost weight (after leasing costs are included) representing 73 percent of total depreciation costs and the movable equipment depreciation cost weight (after leasing costs are included) representing 27 percent of total depreciation costs.

To disaggregate the interest cost weight, we needed to determine the percent of total interest costs for LTCHs that are attributable to government and nonprofit facilities, which we hereafter refer to as the "nonprofit percentage," because price pressures associated with these types of interest costs tend to differ from those for for-profit facilities. We are proposing to use interest costs data from Worksheet A–7 of the 2013 Medicare cost reports for LTCHs, which is the same methodology used for the 2009-based LTCH-specific market basket. The nonprofit percentage determined using this method is 23 percent.

Table VII–3 below provides the proposed detailed capital cost shares obtained from the Medicare cost reports. Ultimately, if finalized, these detailed capital cost shares would be applied to the total capital-related cost weight determined in section VII.D.3.b. of the preamble of this proposed rule to separate the total capital-related cost weight of 9.7 percent into more detailed cost categories and weights.

TABLE VII–3—DETAILED CAPITAL COST WEIGHTS FOR THE PROPOSED 2013-BASED LTCH MARKET BASKET

Cost categories	Proposed cost shares obtained from Medicare cost reports (percent of total costs)	Proposed detailed capital cost shares after allocation of lease expenses (percent of total costs)
Depreciation	22.0	54.8
Building and Fixed Equipment	16.1	40.1
Movable Equipment	5.9	14.7
Interest	9.8	24.4
Government/Nonprofit	2.2	5.6
For-profit	7.6	18.8
Lease	62.3	
Other	5.9	20.8

Note: Total may not add to 100 due to rounding.

e. Proposed 2013-Based LTCH Market Basket Cost Categories and Weights

Table VII–4 below shows the proposed cost categories and weights for the proposed 2013-based LTCH market basket compared to the 2009-based LTCH-specific market basket.

TABLE VII–4—PROPOSED 2013-BASED LTCH COST WEIGHTS COMPARED TO 2009-BASED LTCH COST WEIGHTS

Cost category	Proposed 2013-based LTCH cost weight	2009-based LTCH cost weight
Total	100.0	100.0
Compensation	53.9	54.3
Wages and Salaries	46.6	46.3
Employee Benefits	7.3	8.0
Utilities	2.2	1.8
Electricity	1.0	1.4
Fuel, Oil, and Gasoline	1.1	0.3
Water & Sewerage	0.1	0.1
Professional Liability Insurance	0.9	0.8
All Other Products and Services	33.2	33.3
All Other Products	16.3	19.5
Pharmaceuticals	7.6	8.9
Food: Direct Purchases	1.8	3.4
Food: Contract Services	1.1	0.5
Chemicals	0.7	1.3
Medical Instruments	2.4	2.1
Rubber & Plastics	0.6	1.3
Paper and Printing Products	1.2	1.2
Apparel		0.3
Machinery and Equipment		0.1
Miscellaneous Products	0.8	0.4
All Other Services	16.9	13.7
Labor-Related Services	8.3	5.3
Professional Fees: Labor-related	3.5	2.3
Administrative and Facilities Support Services	0.9	0.5
Installation, Maintenance, and Repair Services	2.0	
All Other: Labor-related Services	1.9	2.6
Nonlabor-Related Services	8.6	8.4
Professional Fees: Nonlabor-related	3.6	5.3
Financial services	2.9	1.0
Telephone Services	0.7	0.5
Postage		0.8
All Other: Nonlabor-related Services	1.4	0.7
Capital-Related Costs	9.7	9.8
Depreciation	5.3	5.7
Fixed Assets	3.9	3.8
Movable Equipment	1.4	1.9
Interest Costs	2.4	2.4
Government/Nonprofit	0.5	0.7
For Profit	1.8	1.7
Other Capital-Related Costs	2.0	1.7

Note: Detail may not add to total due to rounding.

Similar to the 2012-based IRF and 2012-based IPF market baskets, the proposed 2013-based LTCH market basket does not include separate cost categories for Apparel, Machinery and Equipment, and Postage. Due to the small weights associated with these detailed categories and relatively stable price growth in the applicable price proxy, we are proposing to include Apparel and Machinery and Equipment in the Miscellaneous Products cost category and Postage in the All-Other Nonlabor-Related Services cost category. We note that the machinery and equipment expenses are for equipment that is paid for in a given year and not depreciated over the asset's useful life. Depreciation expenses for movable equipment are reflected in the capital-related cost weight of the proposed 2013-based LTCH market basket. For the proposed 2013-based LTCH market basket, we also are proposing to include a separate cost category for Installation, Maintenance, and Repair Services in order to proxy these costs by a price index that better reflects the price changes of labor associated with maintenance-related services.

4. Selection of Proposed Price Proxies

After computing the cost weights for the proposed 2013-based LTCH market basket, it was necessary to select appropriate wage and price proxies to reflect the rate of price change for each expenditure category. With the exception of the proxy for Professional Liability Insurance, all of the proposed proxies for the operating portion of the proposed 2013-based LTCH market basket are based on Bureau of Labor Statistics (BLS) data and are grouped into one of the following BLS categories:

- *Producer Price Indexes*—Producer Price Indexes (PPIs) measure price changes for goods sold in markets other than the retail market. PPIs are preferable price proxies for goods and services that hospitals purchase as inputs because PPIs better reflect the actual price changes encountered by hospitals. For example, we are proposing to use a PPI for prescription drugs, rather than the Consumer Price Index (CPI) for prescription drugs, because hospitals generally purchase drugs directly from a wholesaler. The PPIs that we are proposing to use measure price changes at the final stage of production.
- *Consumer Price Indexes*—Consumer Price Indexes (CPIs) measure change in the prices of final goods and services bought by the typical consumer. Because they may not represent the price encountered by a producer, we are proposing to use CPIs only if an appropriate PPI is not available, or if the expenditures are more like those faced by retail consumers in general rather than by purchasers of goods at the wholesale level. For example, the CPI for food purchased away from home is proposed to be used as a proxy for contracted food services.
- *Employment Cost Indexes*—Employment Cost Indexes (ECIs) measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. Appropriately, they are not affected by shifts in employment mix.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Timeliness implies that the proxy is published regularly, preferably at least once a quarter. Availability means that the proxy is publicly available. Finally, relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. We believe that the proposed PPIs, CPIs, and ECIs selected meet these criteria.

Table VII–7 lists the price proxies that we are proposing to use for the proposed 2013-based LTCH market basket. Below we present a detailed explanation of the price proxies that we are proposing for each cost category weight. We note that many of the proxies that we are proposing to use for the proposed 2013-based LTCH market basket are the same as those used for the 2009-based LTCH-specific market basket. For further discussion on the 2009-based LTCH market basket, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53479).

a. Price Proxies for the Operating Portion of the Proposed 2013-Based LTCH Market Basket

(1) Wages and Salaries

We are proposing to use the ECI for Wages and Salaries for All Civilian Workers in Hospitals (BLS series code CIU1026220000000I) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(2) Employee Benefits

We are proposing to use the ECI for Total Benefits for All Civilian Workers in Hospitals to measure the price growth of this cost category. This ECI is calculated using the ECI for Total Compensation for All Civilian Workers in Hospitals (BLS series code CIU1016220000000I) and the relative importance of wages and salaries within total compensation. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(3) Electricity

We are proposing to use the PPI Commodity for Commercial Electric Power (BLS series code WPU0542) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(4) Fuel, Oil, and Gasoline

We are proposing to change the proxy used for the Fuel, Oil, and Gasoline cost category. The 2009-based LTCH-specific market basket uses the PPI Industry for Petroleum Refineries (BLS series code PCU32411–32411) to proxy these expenses.

For the proposed 2013-based LTCH market basket, we are proposing to use a blend of the PPI Industry for Petroleum Refineries (BLS series code PCU32411–32411) and the PPI Commodity for Natural Gas (BLS series code WPU0531). Our analysis of the Bureau of Economic Analysis' 2007 Benchmark Input-Output data (use table before redefinitions, purchaser's value for NAICS 622000 [Hospitals]), shows that petroleum refineries expenses accounts for approximately 70 percent and natural gas accounts for approximately 30 percent of the fuel, oil, and gasoline expenses. Therefore, we are proposing a blended proxy of 70 percent of the PPI Industry for Petroleum Refineries (BLS series code PCU32411–32411) and 30 percent of the PPI Commodity for Natural Gas (BLS series code WPU0531). We believe that these two price proxies are the most technically appropriate indices available to measure the price growth of the Fuel, Oil, and Gasoline cost category in the proposed 2013-based LTCH market basket.

(5) Water and Sewage

We are proposing to use the CPI for Water and Sewerage Maintenance (All Urban Consumers) (BLS series code CUUR0000SEHG01) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(6) Professional Liability Insurance

We are proposing to proxy price changes in hospital professional liability insurance premiums (PLI) using percentage changes as estimated by the CMS Hospital Professional Liability Index. To generate these estimates, we collected commercial insurance premiums for a fixed level of coverage while holding nonprice factors constant (such as a change in the level of coverage). This is the same price proxy used in the 2009-based LTCH-specific market basket.

(7) Pharmaceuticals

We are proposing to use the PPI Commodity for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(8) Food: Direct Purchases

We are proposing to use the PPI Commodity for Processed Foods and Feeds (BLS series code WPU02) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(9) Food: Contract Services

We are proposing to use the CPI for Food Away From Home (All Urban Consumers) (BLS series code CUUR0000SEFV) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(10) Chemicals

We are proposing to continue to use a four-part blended PPI composed of the PPI Industry for Industrial Gas Manufacturing (BLS series code PCU325120325120P), the PPI Industry for Other Basic Inorganic Chemical Manufacturing (BLS series code PCU32518–32518), the PPI Industry for Other Basic Organic Chemical Manufacturing (BLS series code PCU32519–32519), and the PPI Industry for Soap and Cleaning Compound Manufacturing (BLS series code PCU32561–32561). We are proposing to update the blended weights using 2007 Benchmark I–O data, which we also are proposing to use for the proposed 2013-based LTCH market basket. The 2009-based LTCH-specific market basket included the same blended chemical price proxy, but used the 2002 Benchmark I–O data to determine the weights of the blended chemical price index. The 2007 Benchmark I–O data shows more weight for organic chemical products and less weight for inorganic chemical products compared to the 2002 Benchmark I–O data.

Table VII–5 below shows the proposed weights for each of the four PPIs used to create the blended PPI.

TABLE VII–5—BLENDED CHEMICAL PPI WEIGHTS

Name	Proposed 2013-based LTCH weights	2009-based LTCH weights	NAICS
PPI Industry for Industrial Gas Manufacturing	32%	35%	325120
PPI Industry for Other Basic Inorganic Chemical Manufacturing	17	25	325180
PPI Industry for Other Basic Organic Chemical Manufacturing	45	30	325190
PPI Industry for Soap and Cleaning Compound Manufacturing	6	10	325610

(11) Medical Instruments

We are proposing to use a blend for the Medical Instruments cost category. The 2007 Benchmark Input-Output data shows an approximate 50/50 split between Surgical and Medical Instruments and Medical and Surgical Appliances and Supplies for this cost category. Therefore, we are proposing a blend composed of 50 percent of the PPI Commodity for Surgical and Medical Instruments (BLS code WPU1562) and 50 percent of the PPI Commodity for Medical and Surgical Appliances and Supplies (BLS code WPU1563). The 2009-based LTCH-specific market basket used the single, higher level PPI Commodity for Medical, Surgical, and Personal Aid Devices (BLS series code WPU156). We believe that the proposed price proxy better reflects the mix of expenses for this cost category as obtained from the 2007 Benchmark I–O data.

(12) Rubber and Plastics

We are proposing to use the PPI Commodity for Rubber and Plastic Products (BLS series code WPU07) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(13) Paper and Printing Products

We are proposing to use the PPI Commodity for Converted Paper and Paperboard Products (BLS series code WPU0915) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(14) Miscellaneous Products

We are proposing to use the PPI Commodity for Finished Goods Less Food and Energy (BLS series code WPUFD4131) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(15) Professional Fees: Labor-Related

We are proposing to use the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. It includes occupations such as legal, accounting, and engineering services. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(16) Administrative and Facilities Support Services

We are proposing to use the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(17) Installation, Maintenance, and Repair Services

We are proposing to use the ECI for Total compensation for All Civilian Workers in Installation, Maintenance, and Repair (BLS series code CIU1010000430000I) to measure the price growth of this new cost category. Previously these costs were included in the All Other: Labor-Related Services category and were proxied by the ECI for Total Compensation for Private Industry Workers in Service Occupations (BLS series code CIU2010000300000I). We believe that this index better reflects the price changes of labor associated with maintenance-related services and its incorporation represents a technical improvement to the market basket.

(18) All Other: Labor-Related Services

We are proposing to use the ECI for Total Compensation for Private Industry Workers in Service Occupations (BLS series code CIU2010000300000I) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(19) Professional Fees: Nonlabor-Related

We are proposing to use the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. This is the same price proxy that we are proposing to use for the Professional Fees: Labor-related cost category and the same price proxy used in the 2009-based LTCH-specific market basket.

(20) Financial Services

We are proposing to use the ECI for Total Compensation for Private Industry Workers in Financial Activities (BLS series code CIU201520A000000I) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(21) Telephone Services

We are proposing to use the CPI for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category. This is the same price proxy used in the 2009-based LTCH-specific market basket.

(22) All Other: Nonlabor-Related Services

We are proposing to use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. We believe that using the CPI for All Items Less Food and Energy avoids double counting of changes in food and energy prices as they are already captured elsewhere in the market basket. This is the same price proxy used in the 2009-based LTCH-specific market basket.

b. Price Proxies for the Capital Portion of the Proposed 2013-Based LTCH Market Basket

(1) Capital Price Proxies Prior to Vintage Weighting

We are proposing to apply the same price proxies to the detailed capital-related cost categories as were applied in the 2009-based LTCH-specific market basket, which are described and provided in Table VII–7. We also are proposing to continue to vintage weight the capital price proxies for Depreciation and Interest to capture the long-term consumption of capital. This vintage weighting method is the same method that was used for the 2009-based LTCH-specific market basket and is described in section VII.D.4.b.(2) of the preamble of this proposed rule.

We are proposing to proxy the Depreciation: Building and Fixed Equipment cost category by BEA's Chained Price Index for Nonresidential Construction for Hospitals and Special Care Facilities (BEA Table 5.4.4. Price Indexes for Private Fixed Investment in Structures by Type); the Depreciation: Movable Equipment cost category by the PPI Commodity for Machinery and Equipment (BLS series code WPU11); the Nonprofit Interest cost category by the average yield on domestic municipal bonds (Bond Buyer 20-bond index); the For-Profit Interest cost category by the average yield on Moody's Aaa bonds (Federal Reserve); and the Other Capital-Related cost category by the CPI–U for Rent of Primary Residence (BLS series code CUUS0000SEHA). We believe that these are the most appropriate proxies for LTCH capital-related costs that meet our selection criteria of relevance, timeliness, availability, and reliability.

(2) Vintage Weights for Price Proxies

Because capital is acquired and paid for over time, capital-related expenses in any given year are determined by both past and present purchases of physical and financial capital. The vintage-weighted capital-related portion of the proposed 2013-based LTCH market basket is intended to capture the long-term consumption of capital, using vintage weights for depreciation (physical capital) and interest (financial capital). These vintage weights reflect the proportion of capital-related purchases attributable to each year of the expected life of building and fixed equipment, movable equipment, and interest. We are proposing to use vintage weights to compute vintage-weighted price changes associated with depreciation and interest expenses.

Capital-related costs are inherently complicated and are determined by complex capital-related purchasing decisions, over time, based on such factors as interest rates and debt financing. In addition, capital is depreciated over time instead of being consumed in the same period it is purchased. By accounting for the vintage nature of capital, we are able to provide an accurate and stable annual measure of price changes. Annual non-vintage price changes for capital are unstable due to the volatility of interest rate changes and, therefore, do not reflect the actual annual price changes for LTCH capital-related costs. The capital-related component of the proposed 2013-based LTCH market basket reflects the underlying stability of the capital-related acquisition process.

To calculate the vintage weights for depreciation and interest expenses, we first needed a time series of capital-related purchases for building and fixed equipment and movable equipment. We found no single source that provides an appropriate time series of capital-related purchases by hospitals for all of the above components of capital purchases. The early Medicare cost reports did not have sufficient capital-related data to meet this need. Data we obtained from the American Hospital Association (AHA) did not include annual capital-related purchases. However, we were able to obtain data on total expenses back to 1963 from the AHA. Consequently, we are proposing to use data from the AHA Panel Survey and the AHA Annual Survey to obtain a time series of total expenses for hospitals. We then are proposing to use data from the AHA Panel Survey supplemented with the ratio of depreciation to total hospital expenses obtained from the Medicare cost reports to derive a trend of annual depreciation expenses for 1963 through 2013. We are proposing to separate these depreciation expenses into annual amounts of building and fixed equipment depreciation and movable equipment depreciation as determined earlier. From these annual depreciation amounts, we derived annual end-of-year book values for building and fixed equipment and movable equipment using the expected life for each type of asset category. While data are not available that are specific to LTCHs, we believe that this information for all hospitals serves as a reasonable alternative for the pattern of depreciation for LTCHs. We used the AHA data and methodology to derive the FY 2010-based IPPS capital market basket (78 FR 50604), and the capital components of the 2012-based IRF (80 FR 47062) and 2012-based IPF market baskets (80 FR 46672).

To continue to calculate the vintage weights for depreciation and interest expenses, we also needed to account for the expected lives for building and fixed equipment, movable equipment, and interest for the proposed 2013-based LTCH market basket. We are proposing to calculate the expected lives using Medicare cost report data for LTCHs. The expected life of any asset can be determined by dividing the value of the asset (excluding fully depreciated assets) by its current year depreciation amount. This calculation yields the estimated expected life of an asset if the rates of depreciation were to continue at current year levels, assuming straight-line depreciation. Using this proposed method, we determined the average expected life of building and fixed equipment to be equal to 18 years, and the average expected life of movable equipment to be equal to 8 years. For the expected life of interest, we believe that vintage weights for interest should represent the average expected life of building and fixed equipment because, based on previous research described in the FY 1997 IPPS final rule (61 FR 46198), the expected life of hospital debt instruments and the expected life of buildings and fixed equipment are similar. We note that for the 2009-based LTCH-specific market basket, we used 2009 Medicare cost reports for LTCHs to determine the expected life of building and fixed equipment and movable equipment (77 FR 53467 through 53479). The 2009-based LTCH-specific market basket was based on an expected average life of building and fixed equipment of 20 years and an expected average life of movable equipment of 8 years.

Multiplying these expected lives by the annual depreciation amounts results in annual year-end asset costs for building and fixed equipment and movable equipment. We then calculated a time series, beginning in 1964, of annual capital purchases by subtracting the previous year's asset costs from the current year's asset costs.

For the building and fixed equipment and movable equipment vintage weights, we are proposing to use the real annual capital-related purchase amounts for each asset type to capture the actual amount of the physical acquisition, net of the effect of price inflation. These real annual capital-related purchase amounts are produced by deflating the nominal annual purchase amount by the associated price proxy as provided earlier in this proposed rule. For the interest vintage weights, we are proposing to use the total nominal annual capital-related purchase amounts to capture the value of the debt instrument (including, but not limited to, mortgages and bonds). Using these capital-related purchase time series specific to each asset type, we are proposing to calculate the vintage weights for building and fixed equipment, for movable equipment, and for interest.

The vintage weights for each asset type are deemed to represent the average purchase pattern of the asset over its expected life (in the case of building and fixed equipment and interest, 18 years, and in the case of movable equipment, 8 years). For each asset type, we are proposing to use the time series of annual capital-related purchase amounts available from 2013 back to 1964. These data allow us to derive thirty-three 18-year periods of capital-related purchases for building and fixed equipment and interest, and forty-three 8-year periods of capital-related purchases for movable equipment. For each 18-year period for building and fixed equipment and interest, or 8-year period for movable equipment, we are proposing to calculate annual vintage weights by dividing the capital-related purchase amount in any given year by the total amount of purchases over the entire 18-year or 8-year period. This calculation was done for each year in the 18-year or 8-year period and for each of the periods for which we have data. We then calculated the average vintage weight for a given year of the expected life by taking the average of these vintage weights across the multiple periods of data.

The vintage weights for the capital-related portion of the proposed 2013-based LTCH market basket and the 2009-based LTCH-specific market basket are presented in Table VII–6 below.

TABLE VII–6—PROPOSED 2013-BASED LTCH MARKET BASKET AND 2009-BASED LTCH-SPECIFIC MARKET BASKET VINTAGE WEIGHTS FOR CAPITAL-RELATED PRICE PROXIES

Year[1]	Building and fixed equipment		Movable equipment		Interest	
	2013-based 18 years	2009-based 20 years	2013-based 8 years	2009-based 8 years	2013-based 18 years	2009-based 20 years
1	0.044	0.034	0.104	0.102	0.029	0.021
2	0.046	0.037	0.110	0.108	0.031	0.024
3	0.048	0.039	0.117	0.114	0.034	0.026
4	0.050	0.042	0.124	0.123	0.037	0.029
5	0.051	0.043	0.128	0.129	0.039	0.032
6	0.051	0.045	0.132	0.134	0.042	0.035
7	0.051	0.046	0.140	0.142	0.043	0.037
8	0.052	0.047	0.145	0.149	0.046	0.040
9	0.053	0.049			0.049	0.043
10	0.056	0.051			0.054	0.047
11	0.058	0.053			0.059	0.050
12	0.059	0.053			0.063	0.053
13	0.061	0.053			0.068	0.055
14	0.062	0.054			0.072	0.059
15	0.062	0.055			0.076	0.062
16	0.063	0.057			0.080	0.068
17	0.066	0.059			0.086	0.073
18	0.067	0.059			0.091	0.077
19		0.061				0.082
20		0.062				0.086
Total	1.000	1.000	1.000	1.000	1.000	1.000

Note: Numbers may not add to total due to rounding.

[1] Vintage weight in the last year (for example, year 18 for the proposed 2013-based LTCH market basket) is applied to the most recent data point and prior vintage weights are applied going back in time. For example, year 18 vintage weight would be applied to the 2017q3 price proxy level, year 17 vintage weight would be applied to the 2016q3 price proxy level, etc.

The process of creating vintage-weighted price proxies requires applying the vintage weights to the price proxy index where the last applied vintage weight in Table VII–6 is applied to the most recent data point. We have provided on the CMS Web site an example of how the vintage weighting price proxies are calculated, using example vintage weights and example price indices. The example can be found under the following CMS Web site link: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html* in the zip file titled "Weight Calculations as described in the IPPS FY 2010 Proposed Rule."

c. Summary of Price Proxies of the Proposed 2013-Based LTCH Market Basket

Table VII–7 below shows both the operating and capital price proxies that we are proposing to use for the proposed 2013-based LTCH market basket.

TABLE VII–7—PROPOSED PRICE PROXIES FOR THE PROPOSED 2013-BASED LTCH MARKET BASKET

Cost description	Price proxies	Weight
Total		100.0
Compensation		53.9
Wages and Salaries	ECI for Wages and Salaries for All Civilian Workers in Hospitals.	46.6
Employee Benefits	ECI for Total Benefits for All Civilian Workers in Hospitals	7.3
Utilities		2.2
Electricity	PPI Commodity for Commercial Electric Power	1.0
Fuel, Oil, and Gasoline	Blend of the PPI Industry for Petroleum Refineries and PPI Commodity for Natural Gas.	1.1
Water & Sewerage	CPI–U for Water and Sewerage Maintenance	0.1
Professional Liability Insurance		0.9
Malpractice	CMS Hospital Professional Liability Insurance Premium Index	0.9
All Other Products and Services		33.2
All Other Products		16.3
Pharmaceuticals	PPI Commodity for Pharmaceuticals for human use, prescription.	7.6
Food: Direct Purchases	PPI Commodity for Processed Foods and Feeds	1.8
Food: Contract Services	CPI–U for Food Away From Home	1.1
Chemicals	Blend of Chemical PPIs	0.7
Medical Instruments	Blend of the PPI Commodity for Surgical and Medical Instruments and PPI Commodity for Medical and Surgical Appliances and Supplies.	2.4
Rubber & Plastics	PPI Commodity for Rubber and Plastic Products	0.6
Paper and Printing Products	PPI Commodity for Converted Paper and Paperboard Products.	1.2
Miscellaneous Products	PPI Commodity for Finished Goods Less Food and Energy	0.8
All Other Services		16.9
Labor-Related Services		8.3
Professional Fees: Labor-related	ECI for Total Compensation for Private Industry Workers in Professional and Related.	3.5
Administrative and Facilities Support Services	ECI for Total Compensation for Private Industry Workers in Office and Administrative Support.	0.9
Installation, Maintenance & Repair Services	ECI for Total Compensation for Civilian Workers in Installation, Maintenance, and Repair.	2.0
All Other: Labor-related Services	ECI for Total Compensation for Private Industry Workers in Service Occupations.	1.9
Nonlabor-Related Services		8.6
Professional Fees: Nonlabor-related	ECI for Total Compensation for Private Industry Workers in Professional and Related.	3.6
Financial services	ECI for Total Compensation for Private Industry Workers in Financial Activities.	2.9
Telephone Services	CPI–U for Telephone Services	0.7
All Other: Nonlabor-related Services	CPI–U for All Items Less Food and Energy	1.4
Capital-Related Costs		9.7
Depreciation		5.3
Fixed Assets	BEA chained price index for nonresidential construction for hospitals and special care facilities—vintage weighted (18 years).	3.9
Movable Equipment	PPI Commodity for machinery and equipment—vintage weighted (8 years).	1.4
Interest Costs		2.4
Government/Nonprofit	Average yield on domestic municipal bonds (Bond Buyer 20 bonds)—vintage weighted (18 years).	0.5
For Profit	Average yield on Moody's Aaa bonds—vintage weighted (18 years).	1.8
Other Capital-Related Costs	CPI–U for Rent of Primary Residence	2.0

Note: Sum of the cost weights for the detailed categories may not add to total cost weight for subcategory or total market basket due to rounding.

d. Proposed FY 2017 Market Basket Update for LTCHs

For FY 2017 (that is, October 1, 2016, through September 30, 2017), we are proposing to use an estimate of the proposed 2013-based LTCH market basket to update payments to LTCHs based on the best available data. Consistent with historical practice, we estimate the LTCH market basket update for the LTCH PPS based on IHS Global Insight, Inc.'s (IGI's) forecast using the most recent available data. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets.

Based on IGI's first quarter 2016 forecast with history through the fourth quarter of 2015, the projected market basket update for FY 2017 is 2.7 percent. Therefore, consistent with our historical practice of estimating market basket increases based on the best available data, we are proposing a market basket update of 2.7 percent for FY 2017. Furthermore, because the proposed FY 2017 annual update is based on the most recent market basket estimate for the 12-month period (currently 2.7 percent), we also are proposing that if more recent data become subsequently available (for example, a more recent estimate of the market basket), we would use such data, if appropriate, to determine the FY 2017 annual update in the final rule. (As discussed in greater detail in section V.A.2. of the Addendum to this proposed rule, we are proposing an annual update of 2.7 percent to the LTCH PPS standard Federal payment rate for FY 2017 under proposed § 412.523(c)(3)(xiii) of the regulations.)

Using the current 2009-based LTCH-specific market basket and IGI's first quarter 2016 forecast for the market basket components, the FY 2017 market basket update would be 2.8 percent (before taking into account any statutory adjustment). Therefore, the update based on the proposed 2013-based LTCH market basket is currently 0.1 percentage point lower. This lower update is primarily due to the lower pharmaceutical cost weight in the proposed 2013-based market basket (7.6 percent) compared to the 2009-based LTCH-specific market basket (8.9 percent). This is partially offset by the higher cost weights associated with All Other Services (such as Professional Fees and Installation, Maintenance, and Repair Services) for the proposed 2013-based LTCH market basket relative to the 2009-based LTCH-specific market basket. Table VII–8 below compares the proposed 2013-based LTCH market basket and the 2009-based LTCH-specific market basket percent changes.

TABLE VII–8—PROPOSED 2013-BASED LTCH MARKET BASKET AND 2009-BASED LTCH-PECIFIC MARKET BASKET PERCENTAGE CHANGES, FY 2011 THROUGH FY 2019

Fiscal year (FY)	Proposed 2013-based LTCH market basket index percent change	2009-based LTCH market basket index percent change
Historical data:		
FY 2011	2.3	2.6
FY 2012	1.9	2.3
FY 2013	2.1	2.3
FY 2014	1.8	1.9
FY 2015	1.8	2.2
Average 2011–2015	2.0	2.3
Forecast:		
FY 2016	2.0	2.2
FY 2017	2.7	2.8
FY 2018	3.0	3.1
FY 2019	3.1	3.1
Average 2016–2019	2.7	2.8

Note that these market basket percent changes do not include any further adjustments as may be statutorily required.
Source: IHS Global Insight, Inc. 1st quarter 2016 forecast.

Over the time period covering 2011 through 2015, the average growth rate of the proposed 2013-based LTCH market basket is roughly 0.3 percentage point lower than the 2009-based LTCH-specific market basket. The lower growth rate is primarily a result of the lower pharmaceutical cost weight in the proposed 2013-based market basket compared to the 2009-based LTCH-specific market basket. Historically, the price growth of pharmaceutical costs has exceeded the price growth rates for most of the other market basket cost categories. Therefore, a lower pharmaceutical cost weight would, all else equal, result in a lower market basket update. As stated above, the pharmaceutical cost weights for the proposed 2013-based LTCH market basket and the 2009-based LTCH-specific market basket are based on the 2013 and 2009 Medicare cost report data for LTCHs, respectively.

e. Proposed FY 2017 Labor-Related Share

As discussed in section V.B. of the Addendum to this proposed rule, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS payments to account for differences in LTCH area wage levels (§ 412.525(c)). The labor-related portion of the LTCH PPS standard Federal payment rate, hereafter referred to as the labor-related share, is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index.

The labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market. As discussed in more detail below and similar to the 2009-based LTCH-specific market basket, we classify a cost category as labor-related and include it in the labor-related share if the cost category is defined as being labor-intensive and its cost varies with the local labor market. As stated in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49798), the labor-related share for FY 2016 was defined as the sum of the FY 2016 relative importance of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related Services; Administrative and Facilities Support Services (formerly referred to as Administrative and Business Support Services); All Other: Labor-related Services; and a portion of the Capital

Costs from the 2009-based LTCH-specific market basket.

We proposed to continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market. Given this, based on our definition of the labor-related share and the cost categories in the proposed 2013-based LTCH market basket, we are proposing to include in thelabor-related share for FY 2017 the sum of the FY 2017 relative importance of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related Services; and a portion of the Capital-Related cost weight from the proposed 2013-based LTCH market basket. As noted in section VII.D.3.e. of the preamble of this proposed rule, for the proposed 2013-based LTCH market basket, we have proposed the creation of a separate cost category for Installation, Maintenance, and Repair services. These expenses were previously included in the "All Other" Labor-related Services cost category in the 2009-based LTCH-specific market basket, along with other services, including, but not limited to, janitorial, waste management, security, and dry cleaning/laundry services. Because these services tend to be labor-intensive and are mostly performed at the facility (and, therefore, unlikely to be purchased in the national market), we continue to believe that they meet our definition of labor-related services.

For the development of the 2009-based LTCH-specific market basket, in an effort to more accurately determine the share of professional fees for services such as accounting and auditing services, engineering services, legal services, and management and consulting services that should be included in the labor-related share, we used data from a survey of IPPS hospitals regarding the proportion of those fees that go to companies that are located beyond their own local labor market. The results from this survey were then used to separate a portion of the Professional Fees cost category into labor-related and nonlabor-related costs. These results and our allocation methodology are discussed in more detail in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766). For the proposed 2013-based LTCH market basket, we are proposing to apply these survey results using this same methodology to separate the Professional Fees cost category into Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost categories. We believe that using the survey results serves as an appropriate proxy for the purchasing patterns of professional services for LTCHs because they also are providers of institutional care.

In addition to the professional services listed above, we are proposing to classify expenses under NAICS 55, Management of Companies and Enterprises, into the Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost categories, as was done for the 2009-based LTCH-specific market basket. The NAICS 55 industry is mostly comprised of corporate, subsidiary, and regional managing offices (otherwise referred to as home offices). As stated above, we classify a cost category as labor-related and include it in the labor-related share if the cost category is labor-intensive and if its costs vary with the local labor market. We believe that many of the costs associated with NAICS 55 are labor-intensive and vary with the local labor market. However, data indicate that not all LTCHs with home offices have home offices located in their local labor market. Therefore, we are proposing to include in the labor-related share only a proportion of the NAICS 55 expenses based on the methodology described below.

For the 2009-based LTCH-specific market basket, we used data primarily from the Medicare cost reports and a CMS database of Home Office Medicare Records (HOMER) (a database that provides city and state information (addresses) for home offices) and determined that 13 percent of the total number of LTCHs that had home offices had those home offices located in their respective local labor markets—defined as being in the same Metropolitan Statistical Area (MSA). Therefore, we classified 13 percent of these costs into the "Professional Fees: Labor-related Services" cost category and the remaining 87 percent into the "Professional Fees: Nonlabor-related Services" cost category. For a detailed discussion of this analysis, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53478).

For the proposed 2013-based LTCH market basket, we conducted a similar analysis of home office data. For consistency, we believe that it is important for our analysis on home office data to be conducted on the same LTCHs used to derive the proposed 2013-based LTCH market basket cost weights. The Medicare cost report requires a hospital to report information regarding their home office provider. Approximately 56 percent of LTCHs reported some type of home office information on their Medicare cost report for 2013 (for example, home office number, city, state, zip code, or name). For those providers for which we were able to identify which MSA the LTCH's home office was located, we then compared the home office MSA with the LTCH facility's MSA.

We found that 7 percent of the LTCHs with home offices had those home offices located in the same MSA as their facilities. We then concluded that these providers were located in the same local labor market as their home office. As a result, we are proposing to apportion the NAICS 55 expense data by this percentage. Therefore, we are proposing to classify 7 percent of these costs into the "Professional Fees: Labor-related Services" cost category and the remaining 93 percent of these costs into the "Professional Fees: Nonlabor-related Services" cost category.

Using this proposed method and the IGI forecast for the first quarter 2016 of the proposed 2013-based LTCH market basket, the proposed LTCH labor-related share for FY 2017 would be the sum of the FY 2017 relative importance of each labor-related cost category. Consistent with our proposal to update the labor-related share with the most recent available data, the labor-related share for this proposed rule reflects IGI's first quarter 2016 forecast of the proposed 2013-based LTCH market basket. Table VII–9 below shows the proposed FY 2017 relative importance labor-related share using the proposed 2013-based LTCH market basket and the FY 2016 relative importance labor-related share using the 2009-based LTCH-specific market basket.

TABLE VII–9—LTCH LABOR-RELATED SHARE

	FY 2017 Proposed labor-related share [1]	FY 2016 Final labor related share [2]
Wages and Salaries	46.6	44.6
Employee Benefits	7.3	8.1

TABLE VII–9—LTCH LABOR-RELATED SHARE—Continued

	FY 2017 Proposed labor-related share[1]	FY 2016 Final labor related share[2]
Professional Fees: Labor-related	3.5	2.2
Administrative and Facilities Support Services	0.9	0.5
Installation, Maintenance, and Repair Services[3]	2.1	—
All Other: Labor-related Services	1.9	2.5
Subtotal	62.3	57.9
Labor-related portion of capital (46%)	4.3	4.1
Total Labor-Related Share	66.6	62.0

[1] Based on the proposed 2013-based LTCH Market Basket, IHS Global Insight, Inc. 1st quarter 2016 forecast.
[2] **Federal Register**, 80 FR 49478.
[3] Installation, Maintenance, and Repair services costs were previously included in the All Other: Labor-related Services cost weight of the 2009-based LTCH-specific market basket.

The proposed labor-related share for FY 2017 is the sum of the proposed FY 2017 relative importance of each labor-related cost category, and would reflect the different rates of price change for these cost categories between the base year (2013) and FY 2017. The sum of the proposed relative importance for FY 2017 for operating costs (Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Facilities Support Services, Installation, Maintenance, and Repair Services, All Other: Labor-related Services) would be 62.3 percent, as shown in Table VII–9 above. We are proposing that the portion of capital-related costs that is influenced by the local labor market is estimated to be 46 percent, which is the same percentage applied to the 2009-based LTCH-specific market basket (77 FR 53478). Because the relative importance for capital-related costs under our proposals would be 9.4 percent of the proposed 2013-based LTCH market basket in FY 2017, we are proposing to take 46 percent of 9.4 percent to determine the proposed labor-related share of capital-related costs for FY 2017 (.46 × 9.4). The result would be 4.3 percent, which we are proposing to add to 62.3 percent for the operating cost amount to determine the total proposed labor-related share for FY 2017. Therefore, the labor-related share that we are proposing to use for the LTCH PPS in FY 2017 would be 66.6 percent. This proposed labor-related share is determined using the same methodology as employed in calculating all previous LTCH labor-related shares. We also are proposing that, if more recent data become available, (for example, an updated estimate of the labor-related share) we would use such data to determine the FY 2017 labor-related share for the final rule.

The proposed FY 2017 labor-related share using the proposed 2013-based LTCH market basket is 4.6 percentage points higher than the FY 2016 labor-related share using the 2009-based LTCH-specific market basket. The primary reason for a higher labor-related share, which we describe in more detail below, is a result of the change in the quantity of labor, particularly for professional services, outpacing the change in quantity of products (which are not included in the labor-related share) between 2009 and 2013, which more than offsets the faster relative growth in prices for products.

Roughly three-quarters of the 4.6 percentage point difference is the result of higher base year cost weights for the Professional Fees: Labor-Related, Administrative and Facilities Support Services, All Other: Labor-Related services, and Installation, Maintenance, and Repair services cost categories for the proposed 2013-based LTCH market basket compared to the 2009-based LTCH-specific market basket. We refer to these cost categories collectively as "Labor-Related Services." As stated earlier, installation, maintenance and repair costs were previously classified in the All Other: Labor-Related services cost category of the 2009-based LTCH-specific market basket.

In aggregate, the base year cost weights for the Labor-Related Services cost categories in the proposed 2013-based LTCH market basket are 3.0 percentage points higher than the 2009-based LTCH-specific market basket cost weights. As described in section VII.D.3.e. of the preamble of this proposed rule, the detailed cost categories of the LTCH market basket (including the Labor-Related Services cost categories) are derived by multiplying the "All Other" residual cost weight (which reflects all remaining costs that are not captured in the six major cost category weights calculated using the LTCH Medicare Cost Report data (Wages and Salaries, Employee Benefits, Contract Labor, Professional Liability Insurance, Pharmaceuticals, and Capital)) by the detailed cost weights calculated from the Benchmark I–O data. Therefore, the differences between the Labor-related Services cost weights between the proposed 2013-based LTCH market basket and the 2009-based LTCH-specific market basket are a function of the change in the "All Other" residual cost category weight and changes to the Benchmark I–O data. Approximately 0.6 percentage point of the 3.0 percentage point difference is attributable to the higher "All Other" residual cost category weight of the proposed 2013-based LTCH market basket compared to the 2009-based LTCH-specific market basket, while the remaining 2.4 percentage points is due to the changes in the Benchmark I–O cost weights derived from the 2007 data used in the proposed 2013-based LTCH market basket and the 2002 data used in the 2009-based LTCH-specific market basket.

Roughly one-quarter of the 4.6 percentage point difference between the proposed FY 2017 labor-related share using the proposed 2013-based LTCH market basket and the FY 2016 labor-related share using the 2009-based LTCH-specific market basket is a result of the Compensation cost weight. There are two key factors causing this differential. First, using the 2013 Medicare cost reports, we calculated a Compensation cost weight that is 53.9 percent for the proposed 2013-based LTCH market basket, which reflects both the change in price and change in quantity of compensation. This is 0.9 percentage point higher than the FY 2013 relative importance moving average using the 2009-based LTCH-specific market basket (53.0 percent), which only reflects relative price changes between 2009 and 2013. Second, the relative price growth from

FY 2013 to the payment year between the 2009-based LTCH-specific market basket and the proposed 2013-based LTCH market basket also contributes to the difference. For the 2009-based LTCH-specific market basket, the relative importance for compensation decreases from 53.0 percent in FY 2013 to 52.7 percent in FY 2016, a reduction of 0.3 percentage point. For the proposed 2013-based LTCH market basket, the base weight of 53.9 percent in 2013 is the same as the relative importance in FY 2017. These two factors combined produce the 1.2 percentage point difference in the relative importance for compensation in FY 2016 and FY 2017 as shown in Table VII–9.

As noted above, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to furnish hospital services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect recent mix of goods and services that hospitals purchase (hospital inputs) to furnish inpatient care.

E. Proposed Changes to the LTCH PPS Payment Rates and Other Proposed Changes to the LTCH PPS for FY 2017

1. Overview of Development of the LTCH PPS Standard Federal Payment Rates

The basic methodology for determining LTCH PPS standard Federal prospective payment rates is currently set forth at 42 CFR 412.515 through 412.536. In this section, we discuss the factors that we are proposing to use to update the LTCH PPS standard Federal payment rate for FY 2017, that is, effective for LTCH discharges occurring on or after October 1, 2016 through September 30, 2017. Under the dual rate LTCH PPS payment structure required by statute, beginning with FY 2016, only LTCH discharges that meet the criteria for exclusion from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate specified at § 412.523. (For additional details on our finalized policies related to the dual rate LTCH PPS payment structure required by statute, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623).)

For details on the development of the initial FY 2003 standard Federal rate, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56027 through 56037). For subsequent updates to the LTCH PPS standard Federal rate as implemented under § 412.523(c)(3), we refer readers to the following final rules: RY 2004 LTCH PPS final rule (68 FR 34134 through 34140); RY 2005 LTCH PPS final rule (68 FR 25682 through 25684); RY 2006 LTCH PPS final rule (70 FR 24179 through 24180); RY 2007 LTCH PPS final rule (71 FR 27819 through 27827); RY 2008 LTCH PPS final rule (72 FR 26870 through 27029); RY 2009 LTCH PPS final rule (73 FR 26800 through 26804); FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 44021 through 44030); FY 2011 IPPS/LTCH PPS final rule (75 FR 50443 through 50444); FY 2012 IPPS/LTCH PPS final rule (76 FR 51769 through 51773); FY 2013 IPPS/LTCH PPS final rule (77 FR 53479 through 53481); FY 2014 IPPS/LTCH PPS final rule (78 FR 50760 through 50765); FY 2015 IPPS/LTCH PPS final rule (79 FR 50176 through 50180) and FY 2016 IPPS/LTCH PPS final rule (80 FR 49634 through 49637).

In this FY 2017 proposed rule, we present our proposed policies related to the annual update to the LTCH PPS standard Federal payment rate for FY 2017, which includes the annual market basket update. Consistent with our historical practice of using the best data available, we also are proposing to use more recent data to determine the FY 2017 annual market basket update to the LTCH PPS standard Federal payment rate in the final rule.

The application of the proposed update to the LTCH PPS standard Federal payment rate for FY 2017 is presented in section V.A. of the Addendum to this proposed rule. The components of the proposed annual market basket update to the LTCH PPS standard Federal payment rate for FY 2017 are discussed below, including the reduction to the annual update for LTCHs that fail to submit quality reporting data for FY 2017 as required by the statute (as discussed in section VII.E.2.c. of the preamble of this proposed rule). In addition, we are proposing to make an adjustment to the LTCH PPS standard Federal payment rate to account for the estimated effect of the proposed changes to the area wage level adjustment for FY 2017 on estimated aggregate LTCH PPS payments, in accordance with § 412.523(d)(4) (as discussed in section V.A. of the Addendum to this proposed rule).

2. Proposed FY 2017 LTCH PPS Standard Federal Payment Rate Annual Market Basket Update

a. Overview

Historically, the Medicare program has used a market basket to account for input price increases in the services furnished by providers. The market basket used for the LTCH PPS includes both operating and capital related costs of LTCHs because the LTCH PPS uses a single payment rate for both operating and capital-related costs. We adopted the 2009-based LTCH-specific market basket for use under the LTCH PPS beginning in FY 2013. For additional details on the historical development of the market basket used under the LTCH PPS, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53476). For FY 2017, we are proposing to rebase and revise the 2009-based LTCH-specific market basket. The proposed LTCH market basket is primarily based on Medicare cost report data for LTCHs for 2013. We refer readers to section VII.D. of this preamble of this proposed rule for a complete discussion of the proposed LTCH market basket and a description of the methodologies we are proposing to use for determining the operating and capital-related portions of the proposed 2013-based LTCH market basket.

Section 3401(c) of the Affordable Care Act provides for certain adjustments to any annual update to the LTCH PPS standard Federal payment rate and refers to the timeframes associated with such adjustments as a "rate year" (which are discussed in more detail in section VII.C.2.b. of the preamble of this proposed rule.) We note that because the annual update to the LTCH PPS policies, rates, and factors now occurs on October 1, we adopted the term "fiscal year" (FY) rather than "rate year" (RY) under the LTCH PPS beginning October 1, 2010, to conform with the standard definition of the Federal fiscal year (October 1 through September 30) used by other PPSs, such as the IPPS (75 FR 50396 through 50397). Although the language of sections 3004(a), 3401(c), 10319, and 1105(b) of the Affordable Care Act refers to years 2010 and thereafter under the LTCH PPS as "rate year," consistent with our change in the terminology used under the LTCH PPS from "rate year" to "fiscal year," for purposes of clarity, when discussing the annual update for the LTCH PPS standard Federal payment rate, including the provisions of the Affordable Care Act, we use "fiscal year" rather than "rate year" for 2011 and subsequent years.

b. Proposed Market Basket Under the LTCH PPS for FY 2017

Under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we adopted a 2009-based LTCH-specific market basket for use under the LTCH PPS beginning in FY 2013. The 2009-based LTCH-specific market basket is based solely on the Medicare cost report data submitted by LTCHs and, therefore, specifically reflects the cost structures of only LTCHs. For additional details on the development of the 2009-based LTCH-specific market basket, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53476).

For FY 2017, as noted earlier, we are proposing to rebase and revise the 2009-based LTCH-specific market basket to reflect a 2013 base year. We are proposing to use 2013 cost reports beginning in FY 2013 because these represent the most recent, complete set of Medicare cost report data for purposes of calculating cost weights for the LTCH market basket.

We believe that the proposed 2013-based LTCH market basket appropriately reflects the cost structure of LTCHs, as discussed in greater detail in section VII.D. of the preamble of this proposed rule. In this proposed rule, we are proposing to use the proposed 2013-based LTCH market basket to update the LTCH PPS standard Federal payment rate for FY 2017.

c. Revision of Certain Market Basket Updates as Required by the Affordable Care Act

Section 1886(m)(3)(A) of the Act, as added by section 3401(c) of the Affordable Care Act, specifies that, for rate year 2010 and each subsequent rate year through 2019, any annual update to the LTCH PPS standard Federal payment rate shall be reduced:

- For rate year 2010 through 2019, by the "other adjustment" specified in sections 1886(m)(3)(A)(ii) and (m)(4) of the Act; and
- For rate year 2012 and each subsequent year, by the productivity adjustment (which we refer to as "the multifactor productivity (MFP) adjustment") described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year.

Section 1886(b)(3)(B)(xi)(II) of the Act defines the MFP adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period). Under our methodology, the end of the 10-year moving average of changes in the MFP coincides with the end of the appropriate fiscal year update period. In addition, the MFP adjustment that is applied in determining any annual update to the LTCH PPS standard Federal payment rate is the same adjustment that is required to be applied in determining the applicable percentage increase under the IPPS under section 1886(b)(3)(B)(i) of the Act, as they are both based on a fiscal year. (We refer readers to section IV.A.1. of the preamble of FY 2016 IPPS/LTCH PPS final rule for more information on the current MFP adjustment.)

d. Proposed Adjustment to the LTCH PPS Standard Federal Payment Rate Under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In accordance with section 1886(m)(5) of the Act, as added by section 3004(a) of the Affordable Care Act, the Secretary established the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). The reduction in the annual update to the LTCH PPS standard Federal payment rate for failure to report quality data under the LTCH QRP for FY 2014 and subsequent fiscal years is codified under § 412.523(c)(4) of the regulations. (As previously noted, although the language of section 3004(a) of the Affordable Care Act refers to years 2011 and thereafter under the LTCH PPS as "rate year," consistent with our change in the terminology used under the LTCH PPS from "rate year" to "fiscal year," for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we use "fiscal year" rather than "rate year" for 2011 and subsequent years.) The LTCH QRP, as required for FY 2014 and subsequent fiscal years by section 1886(m)(5)(A)(i) of the Act, applies a 2.0 percentage point reduction to any update under § 412.523(c)(3) for an LTCH that does not submit quality reporting data to the Secretary in accordance with section 1886(m)(5)(C) of the Act with respect to such a year (that is, in the form and manner and at the time specified by the Secretary under the LTCH QRP) (§ 412.523(c)(4)(i)). Section 1886(m)(5)(A)(ii) of the Act provides that the application of the 2.0 percentage points reduction may result in an annual update that is less than 0.0 for a year, and may result in LTCH PPS payment rates for a year being less than such LTCH PPS payment rates for the preceding year (§ 412.523(c)(4)(iii)). Furthermore, section 1886(m)(5)(B) of the Act specifies that the 2.0 percentage points reduction is applied in a noncumulative manner, such that any reduction made under section 1886(m)(5)(A) of the Act shall apply only with respect to the year involved, and shall not be taken into account in computing the LTCH PPS payment amount for a subsequent year (§ 412.523(c)(4)(ii)). We discuss the application of the 2.0 percentage point reduction under § 412.523(c)(4)(i) in our discussion of the proposed annual market basket update to the LTCH PPS standard Federal payment rate for FY 2017 in section VII.E.2.e. of the preamble of this proposed rule. (For additional information on the history of the LTCH QRP, including the statutory authority and the selected measures, we refer readers to section VIII.C. of the preamble of this proposed rule.)

e. Proposed Annual Market Basket Update Under the LTCH PPS for FY 2017

Consistent with our historical practice, we estimate the market basket update and the MFP adjustment based on IGI's forecast using the most recent available data. Based on IGI's first quarter 2016 forecast, the FY 2017 full market basket increase for the LTCH PPS using the proposed 2013-based LTCH market basket is 2.7 percent, as discussed in section VII.D.4.d. of the preamble of this proposed rule. The current estimate of the MFP adjustment for FY 2017 based on IGI's first quarter 2016 forecast is 0.5 percent, as discussed in section IV.B. of the preamble of this proposed rule. In addition, consistent with our historical practice, we are proposing to use a more recent estimate of the market basket increase and the MFP adjustment to determine the FY 2017 market basket update and the MFP adjustment for FY 2017 in the final rule.

For FY 2017, section 1886(m)(3)(A)(i) of the Act requires that any annual update to the LTCH PPS standard Federal payment rate be reduced by the productivity adjustment ("the MFP adjustment") described in section 1886(b)(3)(B)(xi)(II) of the Act. Consistent with the statute, we are proposing to reduce the full FY 2017 market basket increase by the proposed FY 2017 MFP adjustment. To determine the proposed market basket update for LTCHs for FY 2017, as reduced by the MFP adjustment, consistent with our established methodology, we subtracted the proposed FY 2017 MFP adjustment from the proposed FY 2017 market basket update. Furthermore, sections 1886(m)(3)(A)(ii) and 1886(m)(4)(F) of the Act requires that any annual update to the LTCH PPS standard Federal payment rate for FY 2017 be reduced by the "other adjustment" described in paragraph (4), which is 0.75 percentage point for FY 2017. Therefore, following application of the productivity adjustment, we are proposing to further reduce the proposed adjusted market basket update (that is, the proposed full market basket increase less the proposed MFP adjustment) by the "other adjustment" specified by sections 1886(m)(3)(A)(ii) and 1886(m)(4) of the Act. (For additional details on our established methodology for adjusting the market basket increase by the MFP and the "other adjustment" required by the statute, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771).)

For FY 2017, section 1886(m)(5) of the Act requires that, for LTCHs that do not submit quality reporting data as required under the LTCH QRP, any annual update to an LTCH PPS standard Federal payment rate, after application of the adjustments required by section 1886(m)(3) of the Act, shall be further reduced by 2.0 percentage points. Therefore, the proposed update to the LTCH PPS standard Federal payment rate for FY 2017 for LTCHs that fail to submit quality reporting data under the LTCH QRP, the full LTCH PPS market basket increase, subject to an adjustment based on changes in economy-wide productivity ("the MFP adjustment") as required under section 1886(m)(3)(A)(i) of the Act and an additional reduction required by sections 1886(m)(3)(A)(ii) and 1886(m)(4) of the Act, will also be further reduced by 2.0 percentage points.

In this proposed rule, in accordance with the statute, we are proposing to reduce the proposed FY 2017 full market basket increase of 2.7 percent (based on IGI's first quarter 2016 forecast of the proposed 2013-based LTCH market basket) by the proposed FY 2017 MFP adjustment of 0.5 percentage point (based on IGI's first quarter 2016 forecast). Following application of the proposed productivity adjustment, the proposed adjusted market basket update of 2.2 percent (2.7 percent minus 0.5 percentage point) was then reduced by 0.75 percentage point, as required by sections 1886(m)(3)(A)(ii) and 1886(m)(4)(F) of the Act. Therefore, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we are proposing an annual market basket update under to the LTCH PPS standard Federal payment rate for FY 2017 of 1.45 percent (that is, the most recent estimate of the proposed LTCH PPS market basket increase of 2.7 percent, less the proposed MFP adjustment of 0.5 percentage point, and less the 0.75 percentage point required under section 1886(m)(4)(F) of the Act). Accordingly, we are proposing to revise § 412.523(c)(3) by adding a new paragraph (xiii), which would specify that the LTCH PPS standard Federal payment rate for FY 2017 is the LTCH PPS standard Federal payment rate for the previous LTCH PPS year updated by 1.45 percent, and as further adjusted, as appropriate, as described in § 412.523(d). For LTCHs that fail to submit quality reporting data under the LTCH QRP, under § 412.523(c)(3)(xiii) in conjunction with § 412.523(c)(4), we are proposing to further reduce the proposed annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points in accordance with section 1886(m)(5) of the Act. Accordingly, we are proposing an annual update to the LTCH PPS standard Federal payment rate of -0.55 percent (that is, 1.45 percent minus 2.0 percentage points) for FY 2017 for LTCHs that fail to submit quality reporting data as required under the LTCH QRP. As stated above, consistent with our historical practice, we are proposing to use more recent estimate of the market basket and the MFP adjustment to establish an annual update to the LTCH PPS standard Federal payment rate for FY 2017 under § 412.523(c)(3)(xiii) in the final rule. (We note that, consistent with historical practice, we also are proposing to adjusted the proposed FY 2017 LTCH PPS standard Federal payment rate by an area wage level budget neutrality factor in accordance with § 412.523(d)(4) (as discussed in section V.B.5. of the Addendum to this proposed rule).)

3. Proposed Update Under the Payment Adjustment for "Subclause (II)" LTCHs

Under the LTCH PPS payment adjustment for "subclause (II) LTCHs" at § 412.526(c)(1)(ii), we established that, for cost reporting periods beginning during fiscal years after FY 2015, the target amount (used to determine the adjusted payment for Medicare inpatient operating costs under reasonable cost-based reimbursement rules) will equal the hospital's target amount for the previous cost reporting period updated by the applicable annual rate-of-increase percentage specified in § 413.40(c)(3) for the subject cost reporting period (79 FR 50197). For FY 2017, in accordance with § 412.526(c)(1)(ii) of the regulations, we are proposing that, for cost reporting periods beginning during FY 2017, the update to the target amount for the payment adjustment for "subclause (II)" LTCHs would be 2.8 percent, which is the estimated market basket update for FY 2017 to the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis (that is, the applicable annual rate-of-increase percentage under § 413.40(c)(3)), which is discussed in section VI. of the preamble of this proposed rule, is the FY 2017 rate-of-increase percentage estimate for updating the target amounts, and is equal to the estimated percentage increase in the FY 2010-based IPPS operating market basket, in accordance with applicable regulations at § 413.40.

Based on IGI's 2016 first quarter forecast, with historical data through the 2015 fourth quarter, we estimate that the FY 2010-based IPPS operating market basket update for FY 2017 is 2.8 percent (that is, the estimate of the market basket rate-of-increase). Therefore, the proposed rate-of-increase percentage that would be applied to the FY 2016 target amounts in order to determine the FY 2017 target amounts for "subclause (II) LTCHs" under § 412.526(c)(1)(i) is 2.8 percent. This is the same applicable annual rate-of-increase percentage that would be provided for FY 2017 under § 413.40(c)(3), as discussed in section VI. of the preamble of this proposed rule. Consistent with our historical practice of using the best available data, if more recent data become available (for example, a more recent estimate of the market basket increase), we propose to use such data, if appropriate, to determine the FY 2017 rate-of-increase percentage to determine the FY 2017 target amounts for "subclause (II) LTCHs" in the final rule.

F. Proposed Modifications to the "25-Percent Threshold Policy" Payment Adjustments (§§ 412.534 and 412.536)

The "25-percent threshold policy" is a per discharge payment adjustment in the LTCH PPS that is applied to payments for Medicare patient discharges from an LTCH when the number of such patients originating from any single referring hospital is in excess of the applicable threshold for a given cost reporting period (such threshold is generally set at 25 percent, with exceptions for rural and urban single or MSA-dominant hospitals). If an LTCH exceeds the applicable threshold during a cost reporting period, payment for the discharge that puts the LTCH over its threshold and all discharges subsequent to that discharge in the cost reporting period from the referring hospital are adjusted at cost report settlement (discharges not in excess of the threshold are unaffected by the 25-percent threshold policy). Each cost reporting period begins a new threshold determination, so subsequent cost reporting periods are unaffected by failure to meet the applicable percentage threshold requirements in a prior period.

The adjusted payment amount for those discharges that are subject to the current 25-percent threshold policy is calculated as the lesser of the applicable LTCH PPS payment amount or the IPPS equivalent amount. We note that the IPPS equivalent amount under the 25-percent threshold policy differs somewhat from the IPPS comparable per diem amount applicable under the site neutral payment rate policy at § 412.522(c)(1)(i) and the short-stay outlier (SSO) policy at § 412.529(d)(4). For a discussion of the calculation of the IPPS comparable per diem amount under § 412.529(d)(4) and the IPPS equivalent amount under existing §§ 412.534(f) and 412.536(e), including details on the differences in the calculations, we refer readers to our response to comments in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50772).

The 25-percent threshold policy was originally established in the FY 2005 IPPS final rule for LTCH hospital-within-hospitals (HwHs) and satellites (69 FR 49191 through 49214). It addressed patient shifting driven by financial considerations, rather than patient benefit. Specifically, it addressed the negative incentives that result from the co-location of facilities which created incentives for behaviors which result in two hospital stays, and two Medicare payments, for what was essentially one episode of patient care—and a financial windfall for both providers, as compared to acute care hospitals that were not co-located with an LTCH. It also addressed statutory limits for LTCHs, namely concerns that these LTCHs were, in essence, behaving as long-term care "units" of the co-located hospitals (an arrangement prohibited under section 1886(d)(1)(B) of the Act). In order to discourage such activities, CMS initially established a payment adjustment at § 412.534 for discharges in which the patient was admitted to the LTCH location from a co-located referring hospital in excess of an applicable percentage threshold. Implementation was phased in, but ultimately was generally set at a 25-percent threshold after specified phase-in periods. A full discussion of the original 25-percent threshold policy is contained in the FY 2005 IPPS final rule (69 FR 49191 through 49214).

While initially limited to co-located facilities, in keeping with the suggestions of MedPAC and certain other commenters, CMS noted that it would continue to monitor claims data for signs that common ownership between hospitals that did not share a location also encouraged discharge and admission decisions based on reimbursement rather than clinical considerations (69 FR 49202 through 19203). This continued monitoring, including analysis of discharge patterns from the FY 2005 MedPAR files, identified additional patterns of patient shifting and worrisome admission practices between LTCHs and referring hospitals that were not co-located that were similar to the patterns identified in the FY 2004 MedPAR files between co-located LTCHs and their host hospitals. In response to these findings, CMS expanded the 25-percent threshold policy in the RY 2008 LTCH PPS final rule to include all LTCHs and LTCH satellite facilities through the amendment of § 412.534 (including those certain LTCHs which had been grandfathered from the original policy established in the FY 2005 rule) and the addition of § 412.536 (governing patients admitted from hospitals not co-located with the LTCH). A full discussion of this policy can be found in the RY 2008 LTCH PPS final rule (72 FR 26919 through 26944).

The resulting 25-percent threshold policy was to have been phased in over 3 years, and, when fully implemented, the 25-percent threshold policy would have applied to nearly all LTCHs or LTCH satellites and remote locations admitting patients from any hospital, regardless of the location or ownership of the referring hospital. (For the remainder of this section, we refer to the policies under § 412.534 and § 412.536 collectively as the "25-percent threshold policy" unless otherwise indicated.) However, several laws mandated delayed implementation of the policy, including, most recently, section 1206 of the Pathway for Sustainable Growth Rate (SGR) Reform Act (Pub. L. 113–67). Section 1206(b)(1)(B) provides a permanent exemption from the application of the 25-percent threshold policy for co-located LTCHs that were excluded from the original policy in the FY 2005 IPPS final rule. Section 1206(b)(1)(A) extended prior moratoria on the full implementation of the 25-percent threshold policy until cost reporting periods beginning on or after either July 1, 2016 (for LTCHs subject to 42 CFR 412.534) or October 1, 2016 (for LTCHs subject to 42 CFR 412.536). For more details on the various laws that delayed the full implementation of the 25 percent threshold policy, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50356 through 50357).

With the impending expiration of the most recent statutory delay of the full implementation of the 25-percent threshold policy and the recent implementation of a dual rate payment system for the revised LTCH PPS for cost reporting periods beginning on or after October 1, 2015, we have received many questions concerning the mechanics of the revised payment system, especially in relation to the application of the 25-percent threshold policy under § 412.534 and § 412.536, and how those sections will interact. The questions generally involved how CMS would implement the policy for LTCHs with multiple locations. Other questions included how site neutral payment rate discharges would be treated under the policy and how CMS would determine whether a hospital was located in a rural or MSA-dominant area. As a result of the confusion reflected in those questions, we are proposing to revise our existing policies in an effort to simplify the application of the 25-percent threshold policy.

Specifically, we are proposing to sunset both §§ 412.534 and 412.536 and adopt a unified 25-percent threshold policy at new § 412.538. If finalized, this provision would apply to payments for discharges occurring on or after October 1, 2016. The applicable percentage thresholds would generally remain at 25 percent. In keeping with our current policy at § 412.534(h) and § 412.536(a)(2), under proposed new § 412.538(a), the adjustment would not be applicable to "subclause (II)" LTCHs described at section 1886(d)(1)(B)(iv)(II) of the Act and § 412.23(e)(2)(ii) or, consistent with the statute and as codified in the regulations at § 412.534(a) and § 412.536(a)(1)(ii), those HwHs described in § 412.23(e)(2)(i) that meet the criteria in § 412.22(f) ("grandfathered HwHs"). (Section 1206(b)(1)(B) of the Pathway for SGR Reform Act provides for a statutory exclusion from the 25-percent threshold policy for "grandfathered HwHs," which was codified in the regulations at § 412.534(a) and § 412.536(a)(1)(ii) in the FY 2015 IPPS/LTCH PPS final rule at (79 FR 50186)).

In keeping with our current policy at § 412.534(c)(2) and § 412.536(h)(2), we are further proposing that LTCH discharges that reached high-cost outlier status at the referring hospital would not be subject to the 25-percent threshold policy (that is, LTCH discharges which had been high-cost outlier cases at the referring hospital would only be included in an LTCH's total Medicare discharges and, therefore, would not count as having been admitted from that referring hospital. In other words, LTCH discharges that were high-cost outlier cases at the referring hospital would not be counted in the numerator (but would be counted in the denominator) when determining whether the LTCH exceeded the applicable percentage threshold from that referring hospital). As we discussed in the FY 2005 IPPS final rule, we continue to believe that it is appropriate to treat high-cost outlier cases as though they had come from a different hospital because a case which reaches high-cost outlier status has received a full complement of services and, therefore, any transfer from a hospital to an LTCH cannot be said to be premature or inappropriate. In addition, consistent with our current policy, under this proposal, both the LTCH PPS standard Federal payment rate cases and the site neutral payment rate cases would be subject to the 25-percent threshold policy at proposed new § 412.538 and, therefore, would be included in the determination of whether an LTCH has exceeded its threshold. In conjunction with this proposal, we are proposing conforming changes to § 412.522(c)(2) (adjustments for payments under the site neutral payment rate) and § 412.525(d)(5) (adjustments for payments under the LTCH PPS standard Federal payment rate) to include the proposed adjustment for the limitation on LTCH admissions from referring hospitals (that is, the proposed revised 25-percent threshold policy) under new § 412.538. Lastly, we are also proposing that Medicare Advantage (MA) discharges would not be considered under the revised 25-percent threshold policy at proposed new § 412.538, consistent with our current policy. (Consistent with these proposals, for the remainder of this section, when we refer to "Medicare discharges," we mean a hospital's Medicare discharges that were not paid under an MA plan (and in the case of an LTCH, all LTCH PPS discharges, that is, both the LTCH PPS standard Federal payment rate cases and the site neutral payment rate cases).)

Under our proposed revised 25-percent threshold policy at proposed new § 412.538, we are proposing to calculate the numerator and denominator for the "applicable percentage threshold" by using the CMS Certification Number (CCN) on hospital claims submitted to Medicare. Specifically, we would determine whether the applicable percentage threshold was exceeded based on the Medicare discharges from the entire LTCH that were admitted from each referring hospital. The CCN is used on Medicare claims to identify the hospital which discharged the patient, and thus we believe that using the CCN to identify the discharging LTCH and referring hospital is an appropriate and administratively straight-forward process to implement this proposed revision. We believe that this proposed approach would simplify the application of the 25-percent threshold policy because it provides transparency in identifying both the discharging LTCH and the referring hospital. Under this proposed approach, an LTCH's percentage of Medicare discharges from a given referring hospital would be determined during settlement of a cost report by dividing the LTCH's total number of Medicare discharges in the cost reporting period (based on the CCN on the claims) that were admitted directly from a given referring hospital (again determined by the CCN on the referring hospital's claims) that did not receive a high-cost outlier payment (based on the referring hospital's claims) by the LTCH's total number of Medicare discharges in the cost reporting period. In other words, at cost report settlement, each LTCH's Medicare discharges from a given referring hospital (that did not receive a high-cost outlier payment) during that cost reporting period would be evaluated chronologically based on the discharge date from the LTCH, such that the Medicare discharge that results in the LTCH exceeding or remaining in excess of its applicable percentage threshold would be subject to the payment adjustment at proposed new § 412.538(c). Attribution of the Medicare discharge from a specific LTCH and a specific referring hospital would be determined according to the CCN on the Medicare claim submitted by the provider (that is, the LTCH's CCN would be determined from the LTCH's claim; the referring hospital's CCN by its claim), which generally comprises all locations of a single hospital (and for a single LTCH, includes satellite facilities and remote locations, as applicable). For example, the CCN of an LTCH with 3 locations is "902000" and the CCN of a specific referring hospital with 2 locations is "900001." During its cost reporting period, LTCH "902000" has a total of 60 Medicare discharges (10 discharges from the first location, 20 discharges from the second location, and 30 discharges from the third location). Of those 60 Medicare discharges, 25 Medicare discharges (that did not receive a high-cost outlier payment) came directly from hospital "900001" (10 discharges from the first location, and 15 discharges from the second location). LTCH "902000's" percentage of Medicare discharges from referring hospital "900001" would be calculated as 25 divided by 60, or 41.7 percent. The location of the discharging LTCH and the referring hospital is not relevant, and only the aggregate Medicare discharge counts would be used in the proposed calculation when determining if a payment adjustment under proposed new § 412.538 is applicable at cost report settlement.

Under proposed new §§ 412.538 (b) and (c), we are proposing, in general, that payment would be adjusted for LTCH Medicare discharges originating from a single referring hospital during a given cost reporting period when that Medicare discharge results in a percentage of Medicare discharges (that did not receive a high-cost outlier payment) from that referring hospital that exceeds that LTCH's applicable percentage threshold (that is, goes above "25 percent" of that LTCH's total Medicare discharges). In other words, in general, we would continue to calculate separate percentages for each hospital from which an LTCH admits patients, and compare those referring hospitals' percentage of Medicare discharges (excluding those cases that received a high-cost outlier payment) to the LTCH's applicable percentage threshold, and the payment adjustment would then be applied to any of the Medicare discharges that cause the LTCH to exceed or remain in excess of the applicable percentage threshold. Medicare discharges not in excess of the threshold (which includes those that received a high-cost outlier payment at the referring hospital) would continue to be unaffected by the 25-percent threshold policy. As adjusted, the net payment amount to an LTCH for each of its Medicare discharges beyond the applicable percentage threshold would continue to be the lesser of the applicable LTCH PPS payment amount or an IPPS equivalent amount. The IPPS equivalent amount under the current 25-percent threshold policy is set forth in existing regulations at § 412.534(f) and § 412.536(e). As we are proposing to sunset these provisions, we are proposing to codify the existing definition of "IPPS equivalent amount" under our proposed revised 25-percent threshold policy at proposed new § 412.538(f). (For a detailed description of the calculation of the IPPS equivalent amount, we refer readers to the RY 2007 LTCH PPS proposed rule (71 FR 4698 through 4700), which was finalized in the corresponding final rule (71 FR 27875)). As noted previously, the IPPS equivalent amount under the 25-percent threshold policy differs somewhat from the IPPS comparable amount applicable under the site neutral payment rate and the SSO policy (78 FR 50772).

In addition, consistent with our existing policy at § 412.534(d) and § 412.536(c), under proposed new § 412.538(f), we are proposing a 50-percent threshold for rural LTCHs (as defined under § 412.503) in lieu of the generally applicable 25-percent threshold. If finalized, payment to such LTCHs would not be adjusted unless the rural LTCH's Medicare discharges from a single referring hospital (excluding those that received a high-cost outlier payment), which exceeded 50 percent of the LTCH's total Medicare discharges (that is, we would continue to apply an applicable percentage threshold of 50 percent from any single referring hospital to rural LTCHs).

We also are proposing to maintain at proposed new § 412.538(e)(3) the current special treatment of an LTCH located in an MSA with an MSA-dominant hospital at § 412.534(e) and § 412.536(d). As defined in those regulations, an MSA-dominant hospital is a hospital that has discharged more than 25 percent of the total hospital's Medicare discharges in the MSA in which it is located. For LTCHs located in an MSA-dominant area (that is located in an MSA with an MSA-dominant hospital), the LTCH's applicable percentage threshold would continue to be the percentage of total Medicare hospital discharges in the MSA from the MSA-dominant hospital during the LTCH's applicable cost reporting period, but in no case is less than 25 percent or more than 50 percent. (That is, as is the case under our current policy, for an LTCH located in an MSA-dominant area, it would have a single applicable percentage threshold for all of that LTCH's referring hospitals under the special treatment provided under proposed new § 412.538(e)(3). We are proposing to use our existing definition of "MSA-dominant hospital" under both § 412.534(e) and § 412.536(d) of the regulations to also define the term under § 412.103. We are further proposing to codify definitions for the terms "MSA" (which we are proposing to define as an Metropolitan Statistical Area, as defined by the Executive Office of Management and Budget) and "MSA-dominant area" (which we are proposing to define as an MSA in which an MSA-dominant hospital is located) under § 412.103. (Information on OMB's MSA delineations based on the 2010 standards can be found at: *http://www.whitehouse.gov/sites/default/files/omb/assets/fedreg_2010/06282010_metro_standards-Complete.pdf*.)

Under this proposed special treatment at §§ 412.538(e)(2) and (3) for LTCHs with multiple locations, we are further proposing that all locations of the LTCH paid under the LTCH PPS must be rural or located in an MSA-dominant area (as applicable); otherwise the special treatment would not apply and the applicable percentage threshold would be 25 percent. Under our existing regulations, the applicable percentage threshold for each location is determined independently of any other location of the hospital (meaning that, if an LTCH had one rural and one urban location, the applicable percentage threshold for the rural location would be 50 percent and the applicable percentage threshold for the urban location would be 25 percent). However, under our proposal, the applicable percentage threshold would apply to the LTCH as a whole entity (based on its CCN). Therefore, we believe that it would be appropriate to apply the rural and MSA-dominant "special" applicable percentage thresholds based on the LTCH as a whole as well. Furthermore, we believe that LTCHs with locations that do not fall in these special treatment categories would have sufficient access across its locations to admit patients from multiple hospitals such that, as a whole, the LTCH should be able to draw from a diverse enough population to meet the proposed 25-percent threshold criteria. For these reasons, at this time we do not believe that it would be appropriate or necessary to apply these special percentages unless the LTCH is exclusively rural or located exclusively in an MSA-dominant area (as applicable). Therefore, we are proposing to require all locations of an LTCH to be rural or located within an MSA-dominant area in order to qualify for special treatment under proposed new §§ 412.538(e)(2) and (3) (that is, an adjusted applicable percentage threshold).

In summary, for discharges occurring on or after October 1, 2016, we are proposing to establish a single consolidated admission threshold policy (generally a 25-percent threshold policy) at proposed new § 412.538, in conjunction with proposing to sunset the existing 25-percent threshold policies at §§ 412.534 and 412.536, effective October 1, 2016. Under this proposed single 25-percent threshold policy, LTCH PPS payment for LTCH discharges from a single referring hospital in excess of the LTCH's applicable percentage threshold for that referring hospital would be adjusted. We are proposing that the applicable percentage threshold would generally be 25 percent (with proposed special treatment for exclusively rural LTCHs and LTCHs exclusively located in an MSA-dominant area). The proposed 25-percent threshold policy would be applicable to all LTCHs except "subclause (II)" LTCHs and "grandfathered HwHs." Under this proposal, LTCH discharges which reached high-cost outlier status at the referring hospital from which the patient was discharged directly to the LTCH would be treated as though they had come from a different referring hospital and, therefore, would not be counted as a Medicare discharge from that referring hospital. We also are proposing that MA discharges would not be included in this proposed policy. In addition, the proposed revised 25-percent policy would apply to all LTCH PPS discharges (that is, both LTCH PPS standard Federal payment rate and site neutral payment rate cases).

Under this proposal, we would evaluate the "applicable percentage threshold" based on the sum of the locations covered by the LTCH's and referring hospitals' Medicare provider agreement, and would implement this policy using the LTCH's and the referring hospitals' CCN. We are proposing that an LTCH's percentage of Medicare discharges from a given hospital would be determined by dividing the LTCH's number of Medicare discharges in the cost reporting period (based on the LTCH's CCN) that were admitted directly from a given referring hospital (based on the hospital's CCN) that did not receive a high-cost outlier payment during the stay at that referring hospital by the LTCH's total number of Medicare discharges in the cost reporting period (based on the LTCH's CCN). Under proposed new § 412.538, in general, the LTCH PPS payment would be adjusted for LTCH Medicare discharges from a single referring hospital (that did not receive a high cost-outlier payment) that exceed the applicable percentage threshold (generally 25 percent). If an LTCH exceeds its applicable threshold during a cost reporting period, which would be determined at cost report settlement, we are proposing to adjust payment for Medicare discharges in excess of the applicable percentage threshold (including the Medicare discharge which causes the LTCH to exceed the applicable percentage threshold), and Medicare discharges not in excess of the applicable percentage threshold would continue to be unaffected by the 25-percent threshold policy (that is, the payment for such discharges would not be adjusted). As adjusted, the payment amount for a LTCH Medicare discharge that is found to be at or beyond the applicable percentage threshold would continue to receive the lesser of the applicable LTCH PPS payment amount or an IPPS equivalent amount.

G. Proposed Refinement to the Payment Adjustment for "Subclause II" LTCHs

As part of our FY 2015 IPPS/LTCH PPS rulemaking cycle, under the authority provided by section 1206(d)(2) of the Pathway to SGR Reform Act (Pub. L. 113–67), we adopted an adjustment to the LTCH PPS payment for LTCHs classified under section 1886(d)(1)(B)(iv)(II) of the Act ("subclause (II) LTCHs"), which are described in 42 CFR 412.23(e)(2)(ii). Under this adjustment, subclause (II) LTCHs receive payment under the LTCH PPS that is generally equivalent to an amount determined under the reasonable cost-based payment rules for both operating and capital-related costs under 42 CFR part 413 (that is, an amount generally equivalent to an amount determined under the TEFRA payment system methodology, which could be called a "TEFRA-like" methodology). For more information on this adjustment, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50193 through 50197). As initially adopted, this "TEFRA-like" payment adjustment for subclause (II) LTCHs did not incorporate the limitation on charges to Medicare beneficiaries policies under the TEFRA payment system. Alignment of the limitation on charges to beneficiaries and related billing requirements would result in administrative simplification for the cost report submission and settlement process under the payment adjustment for subclause (II) LTCHs specified at § 412.526.

In this proposed rule, we are proposing to revise the limitation on charges to beneficiaries policy and related billing requirements for subclause (II) LTCHs like what is done in the TEFRA payment system context for cost reporting periods beginning on or after October 1, 2016, which would align our beneficiary charge policies (and related billing procedures) with the reasonable cost-based "TEFRA-like" payment adjustment under § 412.526. The adjusted LTCH PPS payment to subclause (II) LTCHs under § 412.526 is considered the full LTCH PPS payment (that is, the LTCH PPS standard Federal payment rate or site neutral payment rate, as applicable), and as such, under current policy that payment applies to the LTCH's costs for services furnished until the high-cost outlier threshold is met (existing § 412.507(a)). Under this proposal, for a subclause (II) LTCH, the Medicare payment would only apply to the LTCH's costs incurred for the days used to calculate the Medicare payment (that is, days for which the patient has a benefit day available). Furthermore, in addition to the applicable Medicare deductible and coinsurance amounts (and for items and services as specified under § 489.20(a)), we would specify that the LTCH may only charge the beneficiary for services provided during the stay that were not the basis for the adjusted LTCH PPS payment amount under § 412.526. If finalized, subclause (II) LTCHs would be treated the same as IPPS-excluded hospitals paid under the TEFRA payment system for purposes of the limitation on charges to beneficiaries and related billing requirements.

In this proposed rule, using the broad authority conferred upon the Secretary under section 123(a)(1) of the BBRA, as amended by section 307(b) of the BIPA, in conjunction with the authority provided under section 1206(d)(2) of Public Law 113–67, we are proposing to revise § 412.507 to limit allowable charges to beneficiaries treated at subclause (II) LTCHs as is done under the TEFRA payment system in order to align our beneficiary charge policies with the reasonable cost-based "TEFRA-like" payment adjustments under § 412.526. Specifically, we are proposing to revise § 412.507 to specify that, for cost reporting periods beginning on or after October 1, 2016, the Medicare payment made to subclause (II) LTCHs (as defined at § 412.23(e)(2)(ii)) only applies to the hospital's costs on the days used to calculate the Medicare payment (that is, days for which the patient has a benefit day available). Furthermore, proposed revised § 412.507 would specify that, for cost reporting periods beginning on or after October 1, 2016, the hospital may only charge the Medicare beneficiary for the applicable deductible and coinsurance amounts (under §§ 409.82, 409.83 and 409.87) for items and services as specified under § 489.20(a), and for services provided during the stay that were not the basis for the adjusted LTCH PPS payment amount under § 412.526.

VIII. Quality Data Reporting Requirements for Specific Providers and Suppliers

We seek to promote higher quality and more efficient healthcare for Medicare beneficiaries. This effort is supported by the adoption of widely agreed-upon quality measures. We have worked with relevant stakeholders to define quality measures for most settings and to measure various aspects of care for most Medicare beneficiaries. These measures assess structural aspects of care, clinical processes, patient experiences with care, care coordination, and improving patient outcomes.

We have implemented quality reporting programs for multiple care settings, including:

- Hospital inpatient services under the Hospital Inpatient Quality Reporting (IQR) Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program);
- Hospital outpatient services under the Hospital Outpatient Quality Reporting (OQR) Program (formerly referred to as the Hospital Outpatient Quality Data Reporting Program (HOP QDRP));
- Care furnished by physicians and other eligible professionals under the Physician Quality Reporting System (PQRS, formerly referred to as the Physician Quality Reporting Program Initiative (PQRI));
- Inpatient rehabilitation facilities under the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP);
- Long-term care hospitals under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP) (also referred to as the LTCHQR Program);
- PPS-exempt cancer hospitals under the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program;
- Ambulatory surgical centers under the Ambulatory Surgical Center Quality Reporting (ASCQR) Program;
- Inpatient psychiatric facilities under the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program;
- Home health agencies under the home health quality reporting program (HH QRP); and
- Hospice facilities under the Hospice Quality Reporting Program.

We have also implemented the End-Stage Renal Disease Quality Incentive Program, Hospital Readmissions Reduction Program, HAC Reduction Program, and Hospital VBP Program (described further below) that link payment to performance.

In implementing the Hospital IQR Program and other quality reporting programs, we have focused on measures that have high impact and support CMS and HHS priorities for improved quality and efficiency of care for Medicare beneficiaries. Our goal for the future is to align the clinical quality measure requirements of the Hospital IQR Program with various other Medicare and Medicaid programs, including those authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act, so that the reporting burden on providers will be reduced. As appropriate, we will consider the adoption of clinical quality measures with electronic specifications so that the electronic collection of performance information is a seamless component of care delivery. Establishing such a system will require interoperability between EHRs and CMS data collection systems, additional infrastructure development on the part of hospitals and CMS, and adoption of standards for capturing, formatting, and transmitting the data elements that make up the measures. However, once these activities are accomplished, adoption of measures that rely on data obtained directly from EHRs will enable us to expand the Hospital IQR Program measure set with less cost and reporting burden to hospitals. We believe that in the near future, collection and reporting of data elements through EHRs will greatly simplify and streamline reporting for various CMS quality reporting programs, and that hospitals will be able to switch primarily to EHR-based data reporting for many measures that are currently manually chart-abstracted and submitted to CMS for the Hospital IQR Program.

We also have implemented a Hospital VBP Program under section 1886(o) of the Act, described in the Hospital Inpatient VBP Program final rule (76 FR 26490 through 26547). We most recently adopted additional policies for the Hospital VBP Program in section IV.I. of the FY 2016 IPPS/LTCH PPS final rule (80 FR 49544 through 49570). Under the Hospital VBP Program, hospitals receive value-based incentive payments based on their performance with respect to performance standards for a performance period for the fiscal year involved. The measures under the Hospital VBP Program must be selected from the measures (other than readmission measures) specified under the Hospital IQR Program as required by section 1886(o)(2)(A) of the Act.

In selecting measures for the Hospital IQR Program, we are mindful of the conceptual framework we have developed for the Hospital VBP Program. Because measures adopted for the Hospital VBP Program must first have been adopted and reported under the Hospital IQR Program, these two programs are linked and the reporting infrastructure for the programs overlap. We view the Hospital VBP Program as the next step in promoting higher quality care for Medicare beneficiaries by transforming Medicare from a passive payer of claims into an active purchaser of quality healthcare for its beneficiaries. Value-based purchasing is an important step to revamping how care and services are paid for, moving increasingly toward rewarding better value, outcomes, and innovations.

We also view the HAC Reduction Program, authorized by section 1886(p) of the Act, as added by section 3008 of the Affordable Care Act, and the Hospital VBP Program, as related but separate efforts to reduce HACs. The Hospital VBP Program is an incentive program that awards payments to hospitals based on quality performance on a wide variety of measures, while the HAC Reduction Program creates a payment adjustment resulting in payment reductions for poorly performing hospitals based on their rates of HACs.

In the preamble of this proposed rule, we are proposing changes to the following Medicare quality reporting systems:

- In section VIII.A, the Hospital IQR Program.
- In section VIII.B., the PCHQR Program.
- In section VIII.C., the LTCH QRP.
- In section VIII.D., the IPFQR Program.

In addition, in section VIII.E. of the preamble of this proposed rule, we are proposing changes to the Medicare and Medicaid EHR Incentive Programs for eligible hospitals and CAHs.

A. Hospital Inpatient Quality Reporting (IQR) Program

1. Background

a. History of the Hospital IQR Program

We refer readers to the FY 2010 IPPS/LTCH PPS final rule (74 FR 43860 through 43861) and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181) for detailed discussions of the history of the Hospital IQR Program, including the statutory history, and to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50217 through 50249) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49692) for the measures we have adopted for the Hospital IQR Program measure set through the FY 2019 payment determination and subsequent years.

b. Maintenance of Technical Specifications for Quality Measures

We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49640 through 49641) for a discussion of the maintenance of technical specifications for quality measures for the Hospital IQR Program. We also refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50202 through 50203) for additional detail on the measure maintenance process.

In addition, we believe that it is important to have in place a subregulatory process to incorporate nonsubstantive updates to the measure specifications for measures we have adopted for the Hospital IQR Program so that these measures remain up-to-date. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53504 through 53505) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203) for our policy for using a subregulatory process to make nonsubstantive updates to measures used for the Hospital IQR Program. We recognize that some changes made to measures undergoing maintenance review are substantive in nature and might not be appropriate for adoption using a subregulatory process. We will continue to use rulemaking to adopt substantive updates made to measures we have adopted for the Hospital IQR Program.

In this proposed rule, we are not proposing any changes to our policies on the measures maintenance process or for using the subregulatory process to make nonsubstantive updates to measures used for the Hospital IQR Program.

c. Public Display of Quality Measures

Section 1886(b)(3)(B)(viii)(VII) of the Act was amended by the Deficit Reduction Act (DRA) of 2005. Section 5001(a) of the DRA requires that the Secretary establish procedures for making information regarding measures submitted available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50776 through 50778) for a more detailed discussion about public display of quality measures.

The *Hospital Compare* Web site is an interactive Web tool that assists beneficiaries by providing information on hospital quality of care to those who need to select a hospital. For more information on measures reported to *Hospital Compare,* we refer readers to the Web site at: *http://www.medicare.gov/hospitalcompare.* Other information not reported to

Hospital Compare may be made available on other CMS Web sites, such as *https://data.medicare.gov.*

In this proposed rule, we are not proposing any changes to these policies.

2. Process for Retaining Previously Adopted Hospital IQR Program Measures for Subsequent Payment Determinations

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53512 through 53513), for our finalized measure retention policy. Pursuant to this policy, when we adopt measures for the Hospital IQR Program beginning with a particular payment determination, we automatically readopt these measures for all subsequent payment determinations unless we propose to remove, suspend, or replace the measures. In this proposed rule, we are not proposing any changes to this policy.

3. Removal and Suspension of Hospital IQR Program Measures

a. Considerations in Removing Quality Measures From the Hospital IQR Program

As discussed above, we generally retain measures from the previous year's Hospital IQR Program measure set for subsequent years' measure sets except when we specifically propose to remove, suspend, or replace a measure. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50185) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203 through 50204) for more information on the criteria we consider for removing quality measures. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49641 through 49643) for more information on the additional factors we consider in removing quality measures and the factors we consider in order to retain measures. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203 through 50204), we also finalized our proposal to clarify the criteria for determining when a measure is "topped-out." In this proposed rule, we are not proposing any changes to these policies.

b. Proposed Removal of Hospital IQR Program Measures for the FY 2019 Payment Determination and Subsequent Years

We are proposing to remove the following 15 measures for the FY 2019 payment determination and subsequent years. Some of these measures we are proposing to remove in their entirety; one of these measures, VTE–6 Incidence of Potentially Preventable Venous Thromboembolism, we are proposing to remove just in the electronic form as discussed further below:

- AMI–2: Aspirin Prescribed at Discharge for AMI (NQF #0142);
- AMI–7a: Fibrinolytic Therapy Received Within 30 minutes of Hospital Arrival;
- AMI–10: Statin Prescribed at Discharge;
- HTN: Healthy Term Newborn (NQF #0716);
- PN–6: Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients (NQF #0147);
- SCIP–Inf–1a: Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision (NQF #0527);
- SCIP–Inf–2a: Prophylactic Antibiotic Selection for Surgical Patients (NQF #0528);
- SCIP–Inf–9: Urinary Catheter Removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with Day of Surgery Being Day Zero;
- STK–4 Thrombolytic Therapy (NQF #0437);
- VTE–3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy (NQF #0373);
- VTE–4: Venous Thromboembolism Patients Receiving Unfractionated Heparin (UFH) with Dosages/Platelet Count Monitoring by Protocol (or Nomogram);
- VTE–5: Venous Thromboembolism Discharge Instructions;
- VTE–6: Incidence of Potentially Preventable Venous Thromboembolism;
- Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care; and
- Participation in a Systematic Clinical Database Registry for General Surgery.

Removal of these measures is discussed in more detail below.

(1) Proposed Removal of Structural Measures

We are proposing to remove two structural measures for the FY 2019 payment determination and subsequent years: (1) Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care; and (2) Participation in a Systematic Clinical Database Registry for General Surgery, because performance on these measures does not result in better patient outcomes—removal factor 4 (80 FR 49641). These measures were originally adopted in the RHQDAPU Program FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43870 through 43872) to monitor participation in systematic clinical database registries for the Hospital IQR Program. By design, the measures do not provide information on patient outcomes, because hospitals are asked only whether they participate in registries. In the future, we will consider other more effective measures to include in the program. As a result, we believe that the burden to retain these measures outweighs the benefits. Therefore, we are proposing to remove these two structural measures from the Hospital IQR Program for the FY 2019 payment determination and subsequent years.

(2) Proposed Removal of "Topped-Out" Chart-Abstracted Measures

We are proposing to remove two measures in their chart-abstracted forms: (1) STK–4: Thrombolytic Therapy (NQF #0437) and (2) VTE–5: VTE Discharge Instructions, because measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made ("topped-out" measures)—removal factor 1 (80 FR 49641). The chart-abstracted version of STK–4 was adopted into the program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51634); and the chart-abstracted version of VTE–5 was adopted into the program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51636). One factor we consider in determining whether a measure should be retained or removed from the program is whether the measure is "topped-out." We have previously adopted two criteria for determining the "topped-out" status of Hospital IQR Program measures: (1) Statistically indistinguishable performance at the 75th and 90th percentiles; and (2) truncated coefficient of variation ≤0.10 (80 FR 49642). These measures meet both of these criteria. We believe that the burdens of retaining these measures outweigh the benefits, and therefore, are proposing to remove the chart-abstracted versions of STK–4 and VTE–5 for the FY 2019 payment determination and subsequent years.

(3) Proposed Removal of Certain eCQMs

We are proposing to remove the electronic versions of AMI–7a, HTN, PN–6, SCIP–Inf–9, VTE–3, VTE–4, VTE–5, VTE–6, STK–4, AMI–2, AMI–10, SCIP–Inf–1a, and SCIP–Inf–2a, beginning with the FY 2019 payment determination. Each measure is discussed in more detail below.

(a) Removal of eCQMs in Alignment With the Medicare and Medicaid EHR Incentive Programs

We are proposing to remove 13 eCQMs from both the Hospital IQR Program and the Medicare and Medicaid EHR Incentive Programs in order for hospitals to focus on a smaller, more specific subset of eCQMs while keeping the programs aligned.

We refer readers to section VIII.A.8.a. and section VIII.A.10.d. of the preamble of this proposed rule for details on our proposed changes to eCQM reporting requirements for the Hospital IQR Program to align with the Medicare and Medicaid EHR Incentive Programs. We also refer readers to section VIII.A.3.b.(3) of the preamble of this proposed rule for our proposals to remove these 13 eCQMs from the Medicare and Medicaid EHR Incentive Programs. We believe that a coordinated reduction in the overall number of eCQMs in both programs would reduce burden on hospitals and improve the quality of reported data by enabling hospitals to focus on a smaller, more specific subset of eCQMs. We are proposing these changes in response to public comments for the Hospital IQR Program in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49694), which recommended that CMS adopt a lesser number of eCQMs.

(i) AMI–7a

We are proposing to remove the AMI–7a: Fibrinolytic Therapy Received Within 30 minutes of Hospital Arrival eCQM, because performance or improvement on this measure does not result in better patient outcomes—removal factor 4 (80 FR 49641). In the FY 2016 IPPS/LTCH PPS final rule, we removed the chart-abstracted version of AMI–7a because the reporting burden outweighed the benefit of posting very few hospitals' measure rates. This measure's specifications resulted in very high denominator exclusion rates. Consequently, the vast majority of abstracted AMI cases were excluded from AMI–7a measure rates. Most acute myocardial infarction (AMI) patients receive percutaneous coronary intervention (PCI) instead of fibrinolytic therapy (80 FR 49647). We do not believe that the mode of reporting (eCQM versus chart-abstracted) would cause the number of cases reported to differ since most AMI patients would still receive PCI instead of fibrinolytic therapy. In the FY 2016 IPPS/LTCH PPS final rule, we retained the electronic version of this measure for alignment purposes with the Medicare and Medicaid EHR Incentive Programs (80 FR 49644). As discussed above, we are proposing to focus on a smaller, more specific subset of eCQMs in both the Hospital IQR and Medicare and Medicaid EHR Incentive Programs. As a result, the burdens related to retaining this measure outweigh the benefits. Therefore, we are proposing to remove the AMI–7a eCQM from the Hospital IQR Program for the FY 2019 payment determination and subsequent years.

(ii) STK–4, AMI–2, AMI–10, SCIP–Inf–1a, and SCIP–Inf–2a

We are proposing to remove the: (1) STK–4: Thrombolytic Therapy (NQF #0437); (2) AMI–2: Aspirin Prescribed at Discharge for AMI (NQF #0142); (3) AMI–10: Statin Prescribed at Discharge; (4) SCIP–Inf–1a: Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision (NQF #0527); and (5) SCIP–Inf–2a: Prophylactic Antibiotic Selection for Surgical Patients (NQF #0528) eCQMs, because measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made—removal factor 1 (80 FR 49641). We note that the NQF has changed the endorsement designations of the AMI–2, AMI–10, SCIP–Inf–1a, and SCIP–Inf–2a chart abstracted measures and eCQM versions to either "reserve status" or "endorsement removed" (available at: *http://www.qualityforum.org/QPS/QPSTool.aspx*), because there is no opportunity for improvement.

We refer readers to section VIII.A.3.b.(2) of the preamble of this proposed rule for our proposal also to remove the chart-abstracted form of the STK–4 measure due to "topped-out" status. The electronic version of the STK–4 measure was adopted into the Hospital IQR Program in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50784) to promote programmatic alignment, as it was a part of a measure set that was already included in the Medicare and Medicaid EHR Incentive Programs' Electronic Reporting Pilot for Eligible Hospitals and CAHs (75 FR 44418 and 76 FR 74489).

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50781), we removed the chart-abstracted versions of AMI–2 and AMI–10 due to "topped-out" status. However, as noted in FY 2015 IPPS/LTCH PPS final rule (79 FR 50245), we readopted these measures, though only in the electronic form, because we believed that we should continue aligning the Hospital IQR Program and the Medicare EHR Incentive Program in order to minimize reporting burden and to facilitate the transition to reporting of eCQMs. We believed that voluntary reporting of these measures would further that aim. In addition, we believed that allowing hospitals the option to electronically report "topped-out" measures would provide them with an opportunity to test the accuracy of their EHR reporting systems.

Similarly, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50208), we removed the chart-abstracted versions of SCIP–Inf–1a and SCIP–Inf–2a, previously referred to as SCIP–Inf–1 and SCIP–Inf–2 respectively, due to their "topped-out" status. However, as stated in that rule, we retained the electronic versions of these measures, because we believed this provided CMS with an opportunity to monitor "topped-out" measures for performance decline. It also simplified alignment between the Hospital IQR and Medicare EHR Incentive Program for eligible hospitals and provided a more straight-forward approach to educate stakeholders on electronic reporting options (79 FR 50208).

As discussed above, we are proposing to focus on a smaller, more specific subset of eCQMs for the Hospital IQR Program and both the Medicare and Medicaid EHR Incentive Programs. Therefore, in light of their "topped out" status, the burden of retaining these measures outweighs the benefits. Thus, we are proposing to remove the STK–4, AMI–2, AMI–10, SCIP–Inf–1a, and SCIP–Inf–2a eCQMs from the Hospital IQR Program for the FY 2019 payment determination and subsequent years.

(b) HTN

We are proposing to remove the HTN: Healthy Term Newborn (NQF #0716) eCQM, because it is no longer feasible to implement the measure specifications—removal factor 7 (80 FR 49642). In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50249), we added HTN, only as an eCQM, not as a claims-based measure. Although the claims-based version of the HTN measure has never been part of the Hospital IQR Program, the claims-based HTN measure concept was used to develop the HTN eCQM. The measure steward has made substantial revisions to the claims-based version of this measure such that the focus is no longer on the number of healthy term newborns, but the number of unexpected complications in term newborns. The numerator of the revised measure has been restructured to assess the presence of severe or moderate complications after term birth, while the original measure looked for the absence of several types of complications after term birth. For the revised measure specifications, we refer readers to: *https://www.cmqcc.org/focus-areas/quality-metrics/unexpected-complications-term-newborns*. In addition, the measure steward is no longer maintaining the claims-based version of HTN or supporting the maintenance of the original eCQM version of HTN that was developed by CMS and adopted in the Hospital IQR Program. Therefore, it is not feasible to continue to include a measure that is no longer supported by the steward. As a result, we are proposing to remove the HTN eCQM from the Program for the FY 2019 payment determination and subsequent years.

(c) PN–6 and SCIP–Inf–9

We are proposing to remove the: (1) PN–6: Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients (NQF #0147) and (2) SCIP–Inf–9: Urinary Catheter Removed on Postoperative Day 1 (POD1) or Postoperative Day 2 ((POD2) with Day of Surgery Being Day Zero) eCQMs, because it is no longer feasible to implement the measure specifications—removal factor 7 (80 FR 49642). While the electronic versions were retained, the chart-abstracted versions of PN–6 and SCIP–Inf–9 were determined to be "topped-out" and were removed from the Hospital IQR Program measure set in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50204 through 50208).

These two eCQMs have undergone significant changes to their logic expression during the previous annual update.[73] There are a number of data capture requirements that cannot be represented adequately in the eCQM form due to their conceptual complexity. Specifically, for PN–6, hospital feedback has indicated difficulties with interpreting several critical timing requirements, such as for intensive care unit populations, emergency department and inpatient admission transitions, steroid therapy, and pre-admission medications. In addition, hospitals raised concern about the inability to account for variation in recording of the interpretation of laboratory results. For SCIP–Inf–9, feedback from hospitals has indicated that it is difficult to interpret the appropriate timing of elements associated with both the insertion and removal of a catheter. This is particularly problematic, because of the variety of patient locations encountered before and after surgery, as well as transfers among units. While these variations for both PN–6 and SCIP–Inf–9 can be accounted for through chart-based manual abstraction, we have had great difficulties in translating and maintaining these options for electronic reporting. Therefore, we are proposing to remove both the PN–6 and SCIP–Inf–9 eCQMs from the Hospital IQR Program for the FY 2019 payment determination and subsequent years.

(d) VTE–3, VTE–4, VTE–5, and VTE–6

We are proposing to remove the four VTE eCQMs: (1) VTE–3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy (NQF #0373); (2) VTE–4: Venous Thromboembolism Patients Receiving Unfractionated Heparin (UFH) with Dosages/Platelet Count Monitoring by Protocol (or Nomogram); (3) VTE–5: Venous Thromboembolism Discharge Instructions; and (4) VTE–6: Incidence of Potentially Preventable Venous Thromboembolism, because it is no longer feasible to implement the measures specifications—removal factor 7 (80 FR 49642). Many of the chart-abstracted versions of these measures were determined to be "topped-out". While the electronic versions of VTE–3 and VTE–4 were retained, the chart-abstracted versions were determined to be "topped-out" and were removed from the Hospital IQR Program measure set in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49643) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50205), respectively. In addition, as described above in section VIII.A.3.b.(2) of the preamble of this proposed rule, we are proposing to remove the chart-abstracted version of VTE–5 for the FY 2019 payment determination and subsequent years due to its "topped-out" status. The electronic version of VTE–5 was adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50784). Finally, the chart-abstracted version of VTE–6, however, continues to be included in the Hospital IQR Program measure set because chart abstractors can manually find required data elements in clinical notes and not in structured data fields.

Nonetheless, a majority of hospitals do not have the ability to capture required data elements, such as diagnostic study results/reports and location of the specific vein in which deep vein thrombosis was diagnosed, in discrete structured data fields to support these eCQMs, because they are often found as free text in clinical notes instead. It is exceedingly difficult for hospitals to implement the measure specifications in the absence of these functional requirements. Furthermore, as discussed above, we are proposing to focus on a smaller, more specific subset of eCQMs in the Hospital IQR Program and both the Medicare and Medicaid EHR Incentive Programs. Therefore, in light of their "topped out" statuses and the infeasibility of implementing the measure specifications, the burden of retaining these measures outweighs the benefits. As a result, we are proposing to remove the VTE–3, VTE–4, VTE–5, and VTE–6 eCQMs from the Hospital IQR Program for the FY 2019 payment determination and subsequent years.

(4) Summary of Measures Proposed for Removal

The table below lists the measures we are proposing for removal. We are inviting public comment on our proposals to remove these 15 measures (eCQMs, structural, and chart-abstracted) from the Hospital IQR Program for the FY 2019 payment determination and subsequent years.

We note that STK–4 and VTE–5 are listed twice—once as an eCQM and again as a chart-abstracted measure.

MEASURES PROPOSED FOR REMOVAL FOR THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Electronic Clinical Quality Measures
• AMI–2: Aspirin Prescribed at Discharge for AMI (NQF #0142)
• AMI–7a: Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival
• AMI–10: Statin Prescribed at Discharge
• HTN: Healthy Term Newborn (NQF #0716)
• PN–6: Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients (NQF #0147)
• SCIP-Inf-1a: Prophylactic Antibiotic Received within 1 Hour Prior to Surgical Incision (NQF #0527)
• SCIP-Inf-2a: Prophylactic Antibiotic Selection for Surgical Patients (NQF #0528)
• SCIP-Inf-9: Urinary Catheter Removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with Day of Surgery Being Day Zero
• STK–4: Thrombolytic Therapy (NQF #0437)
• VTE–3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy (NQF #0373)
• VTE–4: Venous Thromboembolism Patients Receiving Unfractionated Heparin (UFH) with Dosages/Platelet Count Monitoring by Protocol (or Nomogram)

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[73] Technical Release Notes: 2015 Annual Update of 2014 Eligible Hospitals and Eligible Professionals Electronic Clinical Quality Measures (eCQMs). Available at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/EHandEPTRNs.pdf.*

MEASURES PROPOSED FOR REMOVAL FOR THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

Electronic Clinical Quality Measures

- VTE–5: Venous Thromboembolism Discharge Instructions
- VTE–6: Incidence of Potentially Preventable VTE*

Structural Measures

- Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care
- Participation in a Systematic Clinical Database Registry for General Surgery

Chart-Abstracted Measures

- STK–4: Thrombolytic Therapy (NQF #0437)
- VTE–5: VTE Discharge Instructions

* Retained in chart-abstracted form.

4. Previously Adopted Hospital IQR Program Measures for the FY 2018 and FY 2019 Payment Determination and Subsequent Years

The Hospital IQR Program has previously finalized 68 measures as outlined in the table below:

PREVIOUSLY ADOPTED HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Short name	Measure name	NQF #
	NHSN	
CAUTI	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	1717
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI.	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
HCP	Influenza Vaccination Coverage Among Healthcare Personnel	0431
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	1716
	Chart-Abstracted	
ED–1*	Median Time from ED Arrival to ED Departure for patients Admitted ED Patients	0495
ED–2*	Admit Decision Time to ED Departure Time for Admitted Patients	0497
Imm-2	Influenza Immunization	1659
PC–01*	Elective Delivery (Collected in aggregate, submitted via Web-based tool or electronic clinical quality measure).	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
STK–04*	Thrombolytic Therapy	0437
VTE–5*	Venous Thromboembolism Discharge Instructions	+
VTE–6*	Incidence of Potentially Preventable Venous Thromboembolism	+
	Claims-Based Outcome	
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0230
MORT–30–CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery.	2558
MORT–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1893
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization.	0229
MORT–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization.	0468
MORT–30–STK	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Ischemic Stroke	N/A
READM–30–AMI	Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0505

PREVIOUSLY ADOPTED HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

Short name	Measure name	NQF #
READM–30–CABG	Hospital 30-Day, All-Cause, Unplanned, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery.	2515
READM–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1891
READM–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure (HF) Hospitalization.	0330
READM–30–HWR	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
READM–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization.	0506
READM–30–STK	30-Day Risk Standardized Readmission Rate Following Stroke Hospitalization	N/A
READM–30–THA/TKA	Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1551
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	N/A
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	N/A
Hip/knee complications	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550
PSI 04	Death Rate among Surgical Inpatients with Serious Treatable Complications	0351
PSI 90	Patient Safety for Selected Indicators (Composite Measure)	0531
Claims-Based Payment		
AMI payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI).	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF).	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia.	2579
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty.	N/A
MSPB	Payment-Standardized Medicare Spending Per Beneficiary (MSPB)	2158
Electronic Clinical Quality Measures (eCQMs)		
AMI–2	Aspirin Prescribed at Discharge for AMI	0142
AMI–7a	Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival	+
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	0163
AMI–10	Statin Prescribed at Discharge	+
CAC–3	Home Management Plan of Care Document Given to Patient/Caregiver	+
EHDI–1a	Hearing Screening Prior to Hospital Discharge	1354
ED–1*	Median Time from ED Arrival to ED Departure for Admitted ED Patients	0495
ED–2*	Admit Decision Time to ED Departure Time for Admitted Patients	0497
HTN	Healthy Term Newborn	0716
PC–01*	Elective Delivery (Collected in aggregate, submitted via Web-based tool or electronic clinical quality measure).	0469
PC–05	Exclusive Breast Milk Feeding**	0480
PN–6	Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients.	0147
SCIP-Inf-1a	Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision	0527
SCIP-Inf-2a	Prophylactic Antibiotic Selection for Surgical Patients	0528
SCIP-Inf-9	Urinary Catheter Removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with Day of Surgery Being Day Zero.	+
STK–02	Discharged on Antithrombotic Therapy	0435
STK–03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK–04*	Thrombolytic Therapy	0437
STK–05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK–06	Discharged on Statin Medication	0439
STK–08	Stroke Education	+
STK–10	Assessed for Rehabilitation	0441
VTE–1	Venous Thromboembolism (VTE) Prophylaxis	0371
VTE–2	Intensive Care Unit Venous Thromboembolism (VTE) Prophylaxis	0372
VTE–3	Venous Thromboembolism Patients with Anticoagulation Overlap Therapy	0373
VTE–4	Venous Thromboembolism Patients Receiving Unfractionated Heparin with Dosages/Platelet Count Monitoring by Protocol (or Nomogram).	+
VTE–5*	Venous Thromboembolism Discharge Instructions	+
VTE–6*	Incidence of Potentially Preventable Venous Thromboembolism	+
Patient Survey		
HCAHPS	HCAHPS + 3-Item Care Transition Measure (CTM–3)	0166 0228

PREVIOUSLY ADOPTED HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

Short name	Measure name	NQF #
	Structural	
Registry for Nursing Sensitive Care.	Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care	N/A
Registry for General Surgery	Participation in a Systematic Clinical Database Registry for General Surgery	N/A
Patient Safety Culture	Hospital Survey on Patient Safety Culture	N/A
Safe Surgery Checklist	Safe Surgery Checklist Use	N/A

* Measure listed twice, as both chart-abstracted and electronic clinical quality measure.

** Measure name has been shortened. Please refer to annually updated measure specifications on the CMS eCQI Resource Center Page for further information: *https://www.healthit.gov/newsroom/ecqi-resource-center.*

+ Endorsement removed.

PREVIOUSLY ADOPTED HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Short name	Measure name	NQF #
	Claims-Based Payment	
Cellulitis Payment	Cellulitis Clinical Episode-Based Payment Measure	N/A
GI Payment	Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure	N/A
Kidney/UTI Payment	Kidney/Urinary Tract Infection Clinical Episode-Based Payment Measure	N/A

5. Expansion and Updating of Quality Measures

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53510 through 53512) for a discussion of the considerations we use to expand and update quality measures under the Hospital IQR Program. In this proposed rule, we are not proposing any changes to these policies.

6. Proposed Refinements to Existing Measures in the Hospital IQR Program

We are proposing refinements to two claims-based measures: (1) PN Payment: Hospital-Level, Risk-Standardized 30-Day Episode-of-Care Payment Measure for Pneumonia; and (2) PSI 90: Patient Safety and Adverse Events Composite (previously known as the Patient Safety for Selected Indicators Composite Measure). We discuss these proposed refinements in more detail below. In addition, we refer readers to section VIII.A.9.a. of the preamble of this proposed rule where we are inviting public comment on our intent to update the MORT–30–STK measure to include the NIH Stroke Scale as a measure of stroke severity in the risk-adjustment in future rulemaking.

a. Proposed Expansion of the Cohort for the PN Payment Measure: Hospital-Level, Risk-Standardized Payment Associated With a 30-Day Episode-of-Care for Pneumonia (NQF #2579)

(1) Background

For FY 2018 payment determination and subsequent years, we are proposing a refinement of the CMS hospital-level, risk-standardized payment associated with a 30-day episode-of-care for pneumonia (NQF #2579) (PN Payment). The proposed refinement expands the measure cohort to align with the following Hospital IQR Program measures: (1) Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization (NQF #0468) (MORT–30–PN); (2) Hospital 30-day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization (NQF #0506) (READM–30–PN); and (3) Excess Days in Acute Care After Hospitalization for Pneumonia (an improved measure to the previously developed measure entitled "30-day Post-Hospital Pneumonia Discharge Care Transition Composite" (NQF #0707) (PN Excess Days).

The expansion of the measure cohort for the MORT–30–PN and the READM–30–PN was finalized in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49660) and is expected to be publicly reported beginning in July 2016. We refer readers to section VIII.A.7.b. of the preamble of this proposed rule where we are proposing the PN Excess Days measure for inclusion in the Hospital IQR Program for FY 2019 payment determination and subsequent years.

For the purposes of describing the refinement of this measure, we note that "cohort" is defined as the hospitalizations, or "index admissions," that are included in the measure and evaluated to ascertain the total payments made on behalf of the Medicare beneficiary for a 30-day episode-of-care. The cohort is the set of hospitalizations that meets all of the inclusion and exclusion criteria. We are proposing an expansion to this set of hospitalizations.

The previously adopted PN Payment measure (79 FR 50227 through 50231) includes hospitalizations for patients with a principal discharge diagnosis of pneumonia using the International Classification of Diseases, 9th Edition, Clinical Modification (ICD–9–CM), which includes viral and bacterial pneumonia. For more cohort details on the measure as currently implemented, we refer readers to the measure methodology report, with the measure risk adjustment statistical model, in the AMI, HF, PN, and Hip/Knee Arthroplasty Payment Updates zip file on our Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

This proposed measure refinement would expand the measure cohort to include hospitalizations for patients with a: (1) Principal discharge diagnosis of pneumonia, including not only viral or bacterial pneumonia, but also aspiration pneumonia; and (2) principal discharge diagnosis of sepsis (but not severe sepsis) with a secondary diagnosis of pneumonia (including viral or bacterial pneumonia and aspiration pneumonia) coded as present on admission (POA). This refinement to the pneumonia cohort was proposed for several reasons, which were previously discussed in the FY 2016 IPPS/LTCH PPS final rule for the MORT–30–PN and READM–30–PN measures (80 FR 49653 through 49660). We believe that refining this measure is appropriate for the following reasons. First, recent evidence has shown an increase in the use of sepsis as principal discharge diagnosis codes among patients hospitalized with pneumonia.[74] Pneumonia patients with this principal diagnosis code were not included in the original MORT–30–PN and READM–30–PN measure cohorts, and including them would better capture the complete patient population of a hospital with patients receiving clinical management and treatment for pneumonia. In addition, because patients with a principal diagnosis of sepsis are not included in the original MORT–30–PN and READM–30–PN measure specifications, efforts to evaluate changes over time in pneumonia outcomes could be biased as coding practices change. Lastly, a published article[75] also demonstrated wide variation in the use of sepsis codes as principal discharge diagnosis for pneumonia patients across hospitals, which can potentially bias efforts to compare hospital performance on the MORT–30–PN and READM–30–PN measures.

The proposal to align the PN Payment measure cohort with those of the MORT–30–PN, READM–30–PN, and proposed PN Excess Days measures would address the changing coding patterns in which patients with pneumonia are increasingly given a principal discharge diagnosis code of sepsis in combination with a secondary discharge diagnosis of pneumonia that is POA. Moreover, expanding the PN Payment measure cohort would ensure that the measure captures the broader population of patients admitted for pneumonia that may have been excluded from the previously adopted measure. Finally, the expansion of the cohort for the PN Payment measure harmonizes the cohort of this measure with the MORT–30–PN, the READM–30–PN, and the proposed PN Excess Days measures.

The proposed PN Payment measure (MUC15–378), which includes this expanded measure cohort was included on a publicly available document entitled "2015 Measures Under Consideration List" for December 1, 2015 (available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*) and has been reviewed by the NQF Measure Applications Partnership (MAP) Hospital Workgroup. The revised measure was conditionally supported pending the examination of sociodemographic status (SDS) factors and NQF review and endorsement of the measure update, as referenced in the MAP 2016 Final Recommendations Report (available at: *http://www.qualityforum.org/map/*).[76]

In regard to MAP stakeholder concerns that the proposed PN Payment measure may need to be adjusted for SDS, we understand the important role that sociodemographic status plays in the care of patients. However, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of diverse sociodemographic status, because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on hospitals' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

The refined PN Payment measure will be submitted to NQF for reendorsement as part of the next Cost and Resource Use project which is expected in the first quarter of 2017. We will work to minimize any potential confusion when publicly reporting the updated measure to ensure that the refined measure would not be confused with the originally adopted measure.

(2) Overview of Measure Change

The proposed measure refinement expands the cohort. As the measure is currently specified, the cohort includes hospitalizations for patients with a principal discharge diagnosis of pneumonia using the ICD–9–CM, which includes viral and bacterial pneumonia (79 FR 50227 through 50231). This refinement would expand the cohort to also include hospitalizations for patients with a: (1) Principal discharge diagnosis of pneumonia, including not only viral or bacterial pneumonia, but also aspiration pneumonia; and (2) principal discharge diagnosis of sepsis (but not severe sepsis) with a secondary diagnosis of pneumonia (including viral or bacterial pneumonia and aspiration pneumonia) coded as POA.

For the ICD–9–CM and ICD–10–CM codes that define the expanded PN Payment cohort, we refer readers to the 2016 Reevaluation and Re-specifications Report of the Hospital-Level 30-Day Risk-Standardized Pneumonia Payment Measure—Pneumonia Payment Version 3.1 in the AMI, HF, PN, and Hip/Knee Arthroplasty Payment Updates zip file on our Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

The data sources, exclusion criteria, assessment of the total payment outcome, and 3 year reporting period all remain unchanged.

(3) Risk Adjustment

The statistical modeling approach as well as the measure calculation remains unchanged from the previously adopted measure. The risk adjustment approach also remains unchanged; however, to maintain model performance, we conducted variable reselection, or reevaluation of the variables used, to ensure the model risk variables are appropriate for the discharge diagnoses included in the expanded cohort.

The previously adopted pneumonia payment risk-adjustment model includes 48 variables.[77] As a result of the variable reselection process, the revised risk-adjustment model includes a total of 57 variables—37 of the same variables that are in the previously adopted model as well as 20 additional variables. However, there are 11 variables from the previously adopted model that are not included in the revised model. For details on variable reselection and the full measure specifications of the proposed change to the measure, we refer readers to the 2016 Reevaluation and Re-specifications Report of the Hospital-Level 30-Day Risk-Standardized Pneumonia Payment Measure—Pneumonia Payment Version 3.1 in the AMI, HF, PN, and Hip/Knee Arthroplasty Payment Updates zip file on our Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

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[74] Lindenauer PK, Lagu T, Shieh MS, Pekow PS, Rothberg MB. Association of diagnostic coding with trends in hospitalizations and mortality of patients with pneumonia, 2003–2009. Journal of the American Medical Association. Apr 4 2012;307(13):1405–1413.

[75] Rothberg MB, Pekow PS, Priya A, Lindenauer PK. Variation in diagnostic coding of patients with pneumonia and its association with hospital risk-standardized mortality rates: a cross-sectional analysis. Annals of Internal Medicine. Mar 18 2014;160(6):380–388.

[76] Spreadsheet of MAP 2016 Final Recommendations Available at: *http://www.qualityforum.org/map/*.

(4) Estimated Effects of the Cohort Expansion

Using administrative claims data for the FY 2016 payment determination (which included discharges between July 2011 and June 2014), we simulated and analyzed the effects of the proposed cohort refinements on the PN Payment measure (NQF #2579) as if these changes had been applied for FY 2016 payment determination. We note that these statistics are for illustrative purposes only, and we are not proposing to revise measure calculations for the FY 2016 payment determination.

In the FY 2010 IPPS/LTCH PPS final rule (74 FR 43881), we established that if a hospital has fewer than 25 eligible cases combined over a measure's reporting period, we would replace the hospital's data with a footnote indicating that the number of cases is too small to reliably determine how well the hospital is performing. These cases are still used to calculate the measure; however, for hospitals with fewer than 25 eligible cases, the hospital's Risk Standardization Payment (RSP) and RSP interval estimates are not publicly reported for the measure. We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50221), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 24588) for details on our sampling and case thresholds for the FY 2016 payment determination and subsequent years. Expanding the measure cohort to include a broader population of patients as proposed would add a large number of patients, as well as additional hospitals (which would now meet the minimum threshold of 25 eligible cases for public display), to the PN Payment measure (NQF #2579). The increase in the size of the measure cohort proposed in this rule also is estimated to change results for some hospitals as detailed below.

The previously adopted PN Payment measure cohort includes 901,764 patients and 4,685 hospitals for the FY 2016 payment determination (administrative claims from July 2011–June 2014). We noted the following effects for the PN Payment measure if the proposed expanded cohort is applied for FY 2016 payment determinations: (1) The cohort would increase to include an additional 386,143 patients across all hospitals (creating a total measure cohort size of 1,287,907 patients); (2) an additional 81 hospitals would meet the minimum 25 patient case volume threshold over the 3-year reporting period and, as a result, would be publicly reported for the measure; and (3) 31.7 percent of the refined measure cohort would consist of patients who fall into the expanded set of hospitalizations.

The expansion of the cohort leads to an overall increase in the mean national payment of $16,116 when compared to the mean national payment of $14,294 for the previously adopted cohort. This leads to an increase in the RSP outcome of $1,822 or 12.7 percent due to the higher mean payments for patients added to the cohort. An individual hospital's average payment category or reclassification of outlier status of "higher than the U.S. national payment," "no different than the U.S. national payment," or "less than the U.S. national payment" may change as demonstrated in the 2016 Reevaluation and Re-specifications Report of the Hospital-Level 30-Day Risk-Standardized Pneumonia Payment measure—Pneumonia Payment Version 3.1, which can be found in the AMI, HF, PN, and Hip/Knee Arthroplasty Payment Updates zip file on our Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

Overall, we estimate that 1.4 percent of hospitals included in the previously adopted measure would change categorization from greater than average to average payment, 9.3 percent would change from average to greater than average payment, and 8.5 percent would change from average to less than average payment. Finally, 1.8 percent of hospitals would change from less than average to average payment. Therefore, there would be an increase in the number of hospitals considered outliers and a shift in some hospitals' outlier status classification. We reiterate that these statistics are for illustrative purposes only, and we are not proposing to revise measure calculations for the FY 2016 payment determination; our proposal would affect the FY 2018 payment determination and subsequent years.

A detailed description of the refinements to the PN Payment measure (NQF #2579) and the estimated effects of the change are available in the 2016 Reevaluation and Re-specifications Report of the Hospital-Level 30-Day Risk-Standardized Pneumonia Payment Measure—Pneumonia Payment Version 3.1 in the AMI, HF, PN, and Hip/Knee Arthroplasty Payment Updates zip file on our Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

We are inviting public comment on our proposal to refine the Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia (NQF #2579) (PN Payment) measure for the FY 2018 payment determination and subsequent years as described above.

b. Proposed Adoption of Modified PSI 90: Patient Safety and Adverse Events Composite Measure (NQF #0531)

(1) Background

We are proposing to adopt refinements to the Agency for Healthcare Research and Quality (AHRQ) Patient Safety and Adverse Events Composite (NQF #0531) for the Hospital IQR Program beginning with the FY 2018 payment determination and subsequent years. In summary, the PSI 90 measure was refined to reflect the relative importance and harm associated with each component indicator to provide a more reliable and valid signal of patient safety events. We believe refining the PSI 90 measure will provide strong incentives for hospitals to ensure that patients are not harmed by the medical care they receive, a critical consideration in quality improvement.

In the FY 2009 IPPS/LTCH PPS final rule (73 FR 48607 through 48610), we adopted the Complication/Patient Safety for Selected Indicators Composite Measure (NQF #0531) in the Hospital IQR Program beginning with the FY 2010 payment determination as an important measure of patient safety and adverse events. In the FY 2015 IPPS/LTCH PPS final rule, we updated the title of the measure to Patient Safety for Selected Indicators Composite Measure (NQF #0531), to be consistent with the NQF (79 FR 50211). As previously adopted, the PSI 90 measure consisted of eight component indicators: (1) PSI 3 Pressure Ulcer Rate; (2) PSI 6 Iatrogenic Pneumothorax Rate; (3) PSI 7 Central Venous Catheter-Related Blood Stream Infections Rate; (4) PSI 8 Postoperative Hip Fracture Rate; (5) PSI 12 Perioperative Pulmonary Embolism/Deep Vein Thrombosis Rate; (6) PSI 13 Postoperative Sepsis Rate; (7) PSI 14 Postoperative Wound Dehiscence Rate; and (8) PSI 15 Accidental Puncture and Laceration Rate.[78]

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[77] Kim N, Ott L, Hsieh A, et al. 2015 Condition-Specific Measure Updates and Specifications Report, Hospital-Level 30-Day Risk-Standardized Payment Measures—Acute Myocardial Infarction (Version 4.0), Heart Failure (Version 2.0), Pneumonia (Version 2.0). Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.* Accessed Date: March 16, 2016.

The currently adopted eight-indicator version of the measure underwent an extended NQF maintenance reendorsement in the 2014 NQF Patient Safety Committee due to concerns with the underlying component indicators and their composite weights. In the NQF-Endorsed Measures for Patient Safety, Final Report,[79] the NQF Patient Safety Committee deferred their final decision for the PSI 90 measure until the following measure evaluation cycle. In the meantime, AHRQ worked to address many of the NQF stakeholders' concerns about the PSI 90 measure, which subsequently completed NQF maintenance re-review and received reendorsement on December 10, 2015.

The PSI 90 measure's extended NQF reendorsement led to several changes to the measure.[80] First, the name of the PSI 90 measure has changed to "Patient Safety and Adverse Events Composite" (NQF #0531) (herein referred to as the "modified PSI 90"). Second, the modified PSI 90 measure includes the addition of three indicators: (1) PSI 09 Perioperative Hemorrhage or Hematoma Rate; (2) PSI 10 Physiologic and Metabolic Derangement Rate; and (3) PSI 11 Postoperative Respiratory Failure Rate. Third, PSI 12, Perioperative Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT) Rate, and PSI 15, Accidental Puncture or Laceration Rate, have been respecified in the modified PSI 90 measure. Fourth, PSI 07 Central Venous Catheter-Related Blood Stream Infection Rate has been removed in the modified PSI 90 measure. Fifth, the weighting of component indicators in the modified PSI 90 measure is based not only on the volume of each of the patient safety and adverse events, but also the harms associated with the events. We consider these changes to the modified PSI 90 measure to be substantive changes to the measure. Therefore, we are proposing to adopt refinements to the PSI 90 measure for the Hospital IQR Program beginning with the FY 2018 payment determination and subsequent years. We explain the modified PSI 90 measure more fully below, and also refer readers to the measure description on the NQF Web site at: *https://www.qualityforum.org/QPS/MeasureDetails.aspx?standardID=321&print=0&entityTypeID=3*. We are also proposing to modify the reporting periods for FYs 2018 and 2019 payment determinations and subsequent years as detailed further below.

We note that the proposed modified PSI 90 measure (MUC15–604) was included on a publicly available document entitled 2015 Measures Under Consideration for December 1, 2015[81] in compliance with section 1890A(a)(2) of the Act, and was reviewed by the MAP. The MAP supported this measure stating that, "the PSI measures were developed to identify harmful healthcare related events that are potentially preventable. Three additional PSIs have been added to this updated version of the measure. PSIs were better linked to important changes in clinical status with 'harm weights' that are based on diagnoses that were assigned after the complication. This is intended to allow the measure to more accurately reflect the impact of the events."[82] The measure received support for inclusion in the Hospital IQR Program as referenced in the MAP Final Recommendations Report.[83]

(2) Overview of the Measure Changes

First, the name of the PSI 90 measure has changed from the "Patient Safety for Selected Indicators Composite Measure" to the "Patient Safety and Adverse Events Composite" (NQF #0531) to more accurately capture the indicators included in the measure.

Second, the PSI 90 measure has expanded from eight to 10 component indicators. The modified PSI 90 measure is a weighted average of the following 10 risk-adjusted and reliability-adjusted individual component PSI rates:

- PSI 03 Pressure Ulcer Rate;
- PSI 06 Iatrogenic Pneumothorax Rate;
- PSI 08 Postoperative Hip Fracture Rate;
- PSI 09 Postoperative Hemorrhage or Hematoma Rate; *
- PSI 10 Physiologic and Metabolic Derangement Rate; *
- PSI 11 Postoperative Respiratory Failure Rate; *
- PSI 12 Perioperative Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT) Rate;
- PSI 13 Postoperative Sepsis Rate;
- PSI 14 Postoperative Wound Dehiscence Rate; and
- PSI 15 Accidental Puncture or Laceration Rate.[84]

(* Denotes new component for the modified PSI 90 measure)

As stated above, the modified PSI 90 measure also removed PSI 07 Central Venous Catheter-Related Blood Stream Infection Rate, because of potential overlap with the CLABSI measure (NQF #0139), which has been included in the Hospital IQR Program since the FY 2011 IPPS/LTCH PPS final rule (75 FR 50201 through 50202), the HAC Reduction Program since the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), and the Hospital VBP Program since the FY 2013 IPPS/LTCH PPS final rule (77 FR 53597 through 53598).

In response to stakeholder concerns, highlighted in the NQF 2014 Patient Safety Report,[85] the modified PSI 90 measure also respecified two component indicators, PSI 12 and PSI 15. Specifically, for PSI 12 Perioperative PE or DVT Rate, the NQF received public comments concerning the inclusion of: (1) Extracorporeal membrane oxygenation (ECMO) procedures in the denominator; and (2) intra-hospital variability in the documentation of calf vein thrombosis (which has uncertain clinical significance). As such, the modified PSI 12 component indicator no longer includes ECMO procedures in the denominator or isolated deep vein thrombosis of the calf veins in the numerator. PSI 15 also was respecified further to focus on the most serious intraoperative injuries—those that were unrecognized until they required a subsequent reparative procedure. The modified denominator of PSI 15 now is limited to discharges with an abdominal/pelvic operation, rather than including all medical and surgical discharges. In addition, to identify events that are more likely to be clinically significant and preventable, the PSI 15 numerator was modified to require both: (1) A diagnosis of an accidental puncture and/or laceration; and (2) an abdominal/pelvic reoperation one or more days after the index surgery.

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[78] NQF-Endorsed Measures for Patient Safety, Final Report. Available at: *http://www.qualityforum.org/Publications/2015/01/NQF-Endorsed_Measures_for_Patient_Safety,_Final_Report.aspx.*

[79] NQF-Endorsed Measures for Patient Safety, Final Report available at: *http://www.qualityforum.org/Publications/2015/01/NQF-Endorsed_Measures_for_Patient_Safety,_Final_Report.aspx.http://www.qualityforum.org/Publications/2015/01/NQF-Endorsed_Measures_for_Patient_Safety,_Final_Report.aspx.*

[80] National Quality Forum QPS Measure Description for "Patient Safety for Selected Indicators (modified version of PSI90) (Composite measure)" found at: *https://www.qualityforum.org/QPS/MeasureDetails.aspx?standardID=321&print=0&entityTypeID=3.*

[81] 2015 Measures Under Consideration List Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367.*

[82] MAP Final Recommendations. Available at: *http://www.qualityforum.org/map/.*

[83] MAP Final Recommendations. Available at: *http://www.qualityforum.org/map/.*

[84] *http://www.qualityforum.org/QPS/0531.*

[85] NQF Endorsed Measures for Patient Safety, Final Report. Available at: *http://www.qualityforum.org/Publications/2015/01/NQF-Endorsed_Measures_for_Patient_Safety,_Final_Report.aspx.*

Finally, the NQF Patient Safety Review Committee raised concerns about the weighting scheme of the component indicators. In prior versions of the measure, the weights of each component PSI were based solely on volume (numerator rates). In the modified PSI 90 measure, the rates of each component PSI are weighted based on statistical and empirical analyses of volume, excess clinical harm associated with the PSI, and disutility (individual preference for a health state linked to a harm, such as death or disability. The final weight for each component indicator is the product of harm weights and volume weights (numerator weights). Harm weights are calculated by multiplying empirical estimates of excess harms associated with the patient safety event by the utility weights linked to each of the harms. Excess harms are estimated using statistical models comparing patients with a safety event to those without a safety event in a Medicare fee-for-service sample. Volume weights are calculated based on the number of safety events for the component indicators in an all-payer reference population. For more information on the modified PSI 90 measure and component indicators, we refer readers to Quality Indicator Empirical Methods available online at: *www.qualityindicators.ahrq.gov.*

(3) Risk Adjustment

The risk adjustment and statistical modeling approaches of the models remain unchanged in the modified PSI 90 measure. In summary, the predicted value for each case is computed using a modeling approach that includes, but is not limited to, applying a Generalized Estimating Equation (GEE) hierarchical model (logistic regression with hospital random effect) and covariates for gender, age, Modified MS–DRG (MDRG), Major Diagnostic Category, transfer in, point of origin not available, procedure days not available, and AHRQ comorbidity (COMORB).

The expected rate for each of the indicators is computed as the sum of the predicted value for each case divided by the number of cases for the unit of analysis of interest (that is, the hospital). The risk-adjusted rate for each of the indicators is computed using indirect standardization as the observed rate divided by the expected rate, multiplied by the reference population rate. For more details about risk adjustment, we refer readers to: *http://www.qualityindicators.ahrq.gov/Downloads/Resources/Publications/2015/Empirical_Methods_2015.pdf.* As stated above, we are not proposing any changes to the risk adjustment for this measure.

(4) Proposed Reporting Periods

The PSI 90 measure is a claims-based measure that has been calculated using 24-months of data. For the FY 2018 and FY 2019 payment determinations, measure rates would be calculated using reporting periods of July 1, 2014 through June 30, 2016 and July 1, 2015 through June 30, 2017, respectively. However, because hospitals began ICD–10–CM/PCS implementation on October 1, 2015, these reporting periods for the FY 2018 and FY 2019 payment determinations would require using both ICD–9 and ICD–10 claims data to calculate measure performance.

Since the ICD–10 transition was implemented on October 1, 2015, we have been monitoring our systems, and so far, claims are processing normally. The measure steward, AHRQ, has been reviewing the measure for any potential issues related to the conversion of approximately 70,000 ICD–10 coded operating room procedures[86] (*https://www.cms.gov/icd10manual/fullcode_cms/P1616.html*), which could directly affect the modified PSI 90 component indicators. In addition, to meet program requirements and implementation schedules, our system would require an ICD–10 risk-adjusted version of the AHRQ QI PSI software[87] by December 2016 for the FY 2018 payment determination year. At this time, a risk adjusted ICD–10 version of the modified PSI 90 Patient Safety and Adverse Events Composite software is not expected to be available until late CY 2017.

To address the above issues, we are proposing to modify the reporting periods for the FYs 2018 and 2019 payment determinations and beyond. For the FY 2018 payment determination, we are proposing to use a 15-month reporting period spanning July 1, 2014 through September 30, 2015. The 15-month reporting period would only apply to the FY 2018 payment determination and would only use ICD–9 data. For the FY 2019 payment determination, we are proposing to use a 21-month reporting period spanning October 1, 2015 through June 30, 2017. The 21-month reporting period would only apply to the FY 2019 payment determination and would only use ICD–10 data. For all subsequent payment determinations after FY 2019, we are proposing to use the standard 24-month reporting period, which would only use ICD–10 data. In order to align the modified PSI 90 measure and the use of ICD–9 and ICD–10 data across CMS hospital quality programs, we are proposing similar modifications for FYs 2018 and 2019 payment determinations and beyond in the HAC Reduction Program, as set forth in section IV.I.5.b. of the preamble of this proposed rule, and similar modifications to the performance period for the Hospital VBP Program FY 2018 program year, as set forth in section IV.H.2. of the preamble of this proposed rule.

Prior to deciding to propose abbreviated reporting periods for the FY 2018 and FY 2019 payment determinations, we took several factors into consideration, including the recommendations of the measure steward, the feasibility of using a combination of ICD–9 and ICD–10 data without the availability of the appropriate measure software, minimizing provider burden, program implementation timelines, and the reliability of using shortened reporting periods, as well as the importance of continuing to publicly report this measure. We believe that using a 15-month reporting period for the FY 2018 payment determination and a 21-month reporting period for the FY 2019 payment determination best serves the need to provide important information on hospital patient safety and adverse events by allowing sufficient time to process the claims data and calculate the measures, while minimizing reporting burden and program disruption. We will continue to test ICD–10 data that are submitted in order to ensure the accuracy of measure calculations, to monitor and assess the translation of measure specifications to ICD–10 as well as potential coding variation, and to assess any impacts on measure performance.

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[86] International Classification of Diseases, (ICD–10–CM/PCS) Transition—Background. Available at: *http://www.cdc.gov/nchs/icd/icd10cm_pcs_background.htm.*

[87] The AHRQ QI Software is the software used to calculate PSIs and the composite measure. More information is available at: *http://www.qualityindicators.ahrq.gov/Downloads/Resources/Publications/2015/Empirical_Methods_2015.pdf.*

We note that a prior reliability analysis of the PSI 90 measure (not the modified PSI 90 measure) showed that the majority of hospitals attain a moderate or high level of reliability after a 12-month reporting period.[88] Although the modified PSI 90 measure has undergone substantial changes since this analysis, we believe that measure scores would continue to be reliable for the above proposed reporting periods, because the NQF, which reendorsed the modified version, found it to be reliable using 12 months of data.[89] In establishing the revised reporting periods for the modified PSI 90 measure, we also relied upon an analysis by Mathematica Policy Research, a CMS contractor, which found that the measure was most reliable with a 24-month reporting period and unreliable with a reporting period of less than 12 months.[90] Therefore, we believe that the proposed abbreviated reporting periods for the modified PSI 90 measure would produce reliable data because the reporting periods are still greater than 12 months.

(5) Proposed Adoption of the Modified PSI 90 Measure

In summary, the PSI 90 measure was revised to reflect the relative importance and harm associated with each component indicator to provide a more reliable and valid signal of patient safety events. We believe that adopting the modified PSI 90 measure would continue to provide strong incentives for hospitals to ensure that patients are not harmed by the medical care they receive, which is a critical consideration in quality improvement.

We are inviting public comment on our proposal to adopt the modified PSI 90 measure (NQF #0531) for the Hospital IQR Program beginning with the FY 2018 payment determination. We will continue to use the currently adopted eight-indicator version of the PSI 90 measure in the Hospital IQR Program for FY 2017. We also are inviting public comment on the proposals to revise the reporting periods for this measure as described above: (1) A 15-month reporting period using only ICD–9 data for the FY 2018 payment determination; (2) a 21-month reporting period using only ICD–10 data for the FY 2019 payment determination; and (3) a 24-month reporting period using only ICD–10 data for the FY 2020 payment determination and subsequent years.

7. Proposed Additional Hospital IQR Program Measures for the FY 2019 Payment Determination and Subsequent Years

We are proposing to add four new measures to the Hospital IQR Program for the FY 2019 payment determination and subsequent years. We are proposing to adopt three clinical episode-based payment measures:

- Aortic Aneurysm Procedure Clinical Episode-Based Payment (AA Payment) Measure;
- Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment (Chole and CDE Payment) Measure; and
- Spinal Fusion Clinical Episode-Based Payment (SFusion Payment) Measure.

In addition, we are proposing to adopt one required outcome measure: Excess Days in Acute Care After Hospitalization for Pneumonia.

The proposed measures were included on a publicly available document entitled "2015 Measures Under Consideration" [91] in compliance with section 1890A(a)(2) of the Act, and they were reviewed by the MAP as discussed in its MAP Pre-Rulemaking Report and Spreadsheet of MAP 2016 Final Recommendations.[92]

Below, we discuss each of the above measures in more detail.

a. Proposed Adoption of Three Clinical Episode-Based Payment Measures

(1) Background

Clinical episode-based payment measures are clinically coherent groupings of healthcare services that can be used to assess providers' resource use. Combined with other clinical quality measures, they contribute to the overall picture of providers' clinical effectiveness and efficiency. Episode-based performance measurement allows meaningful comparisons between providers based on resource use for certain clinical conditions or procedures, as noted in the NQF report for the "Episode Grouper Evaluation Criteria" project available at: *http://www.qualityforum.org/Publications/2014/09/Evaluating_Episode_Groupers__A_Report_from_the_National_Quality_Forum.aspx* and in various peer-reviewed articles.[93] We are proposing three clinical episode-based payment measures for inclusion in the Hospital IQR Program beginning with the FY 2019 payment determination: (1) Aortic Aneurysm Procedure Clinical Episode-Based Payment (AA Payment) Measure; (2) Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment (Chole and CDE Payment) Measure; and (3) Spinal Fusion Clinical Episode-Based Payment (SFusion Payment) Measure. The proposed measures capture Medicare payment for services related to the episode procedure and take into account beneficiaries' clinical complexity as well as geographic payment differences.

We are proposing these clinical episode-based measures to supplement the Hospital IQR Program's Medicare Spending per Beneficiary (MSPB) Measure. The proposed measures also support our mission to provide better healthcare for individuals, better health for populations, and lower costs for healthcare. We note that these measures were reviewed by the MAP and did not receive support for adoption into the Hospital IQR Program, as discussed in its MAP Pre-Rulemaking Report and Spreadsheet of MAP 2016 Final Recommendations.[94] The result of the MAP vote for the proposed measures was as follows: (1) Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure: 8 percent support, 32 percent conditional support, and 60 percent do not support; (2) Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure: 20 percent support, 28 percent conditional support, and 52 percent do not support; and (3) Spinal

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[88] Mathematica Policy Research (November 2011). Reporting period and reliability of AHRQ, CMS 30-day and HAC Quality Measures—Revised. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/Downloads/HVBP_Measure_Reliability-.pdf*.

[89] "Patient Safety 2015 Final Report" is available at: *http://www.qualityforum.org/Publications/2016/02/Patient_Safety_2015_Final_Report.aspx*.

[90] Mathematica Policy Research (November 2011). Reporting period and reliability of AHRQ, CMS 30-day and HAC Quality Measures—Revised. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-AssessmentInstruments/hospital-value-basedpurchasing/Downloads/HVBP_Measure_Reliability-.pdf*.

[91] Measure Applications Partnership: List of Measures Under Consideration (MUC) for December 1, 2015. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*.

[92] Spreadsheet of MAP 2016 Final Recommendations Available at: *http://www.qualityforum.org/map/*.

[93] For example: Hussey, P. S., Sorbero, M. E.,Mehrotra, A., Liu, H., & Damberg, S. L.: (2009). Episode-Based Performance Measurement and Payment: Making It a Reality. Health Affairs, 28(5), 1406–1417. Doi:10.1377/hlthaff.28.5.1406.

[94] Spreadsheet of MAP 2016 Final Recommendations. Available at: *http://www.qualityforum.org/map/*.

Fusion Clinical Episode-Based Payment Measure: 16 percent support, 36 percent conditional support, and 48 percent do not support. MAP stakeholders expressed concerns that the proposed measures: (1) Overlap with the Medicare Spending per Beneficiary (MSPB) Measure;[95] (2) are not NQF-endorsed; (3) may need to be adjusted for sociodemographic status (SDS); and (4) fail to link outcomes to quality because they do not reflect appropriateness of care.

In response to MAP stakeholder concerns that the clinical episode-based payment measures overlap with the MSPB measure, we note that unlike the overall MSPB measure, the clinical episode-based payment measures assess payment variation at the procedure level and only include services that are clinically related to the named episode procedure (for example, the spinal fusion measure includes inpatient admissions for "medical back problems" that occur following the initial spinal fusion procedure since the admission is likely a result of complications from the initial procedure).

With respect to MAP stakeholder concerns that the clinical episode-based payment measures are not NQF-endorsed, section 1886(b)(3)(B)(IX)(bb) of the Act provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We considered other existing measures related to payment that have been endorsed by the NQF and other consensus organizations, but we were unable to identify any NQF-endorsed (or other consensus organization endorsed) payment measures that assess the aortic aneurysm procedure, cholecystectomy and common duct exploration, or spinal fusion. However, these proposed clinical episode-based payment measures will be submitted to NQF for endorsement as part of the next Cost and Resource Use project.

In regard to MAP stakeholder concerns that the clinical episode-based payment measures may need to be adjusted for SDS, we refer readers to section VIII.A.6.a.(1) of the preamble of this proposed rule for a discussion of our policy on SDS factors. Finally, regarding MAP stakeholder concerns that the clinical episode-based payment measures fail to link outcomes to quality because they do not reflect appropriateness of care, we believe that the proposed measures cover topics of critical importance to quality in the inpatient hospital setting. Hospitals have a significant influence on Medicare spending during the episode surrounding a hospitalization, through the provision of appropriate, high-quality care before and during inpatient hospitalization and through proper hospital discharge planning, care coordination, and care transitions. While we recognize that high or low payments to hospitals are difficult to interpret in isolation, high payments for services may implicitly be associated with poor quality of care (for example, preventable readmissions, procedure complications, or emergency room usage).

Although the MAP did not support inclusion of these clinical episode-based payment measures in the Hospital IQR Program,[96] stakeholders have requested to have more condition-specific and procedure-specific measures, similar to the MSPB measure included in the Hospital IQR Program, as described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51623). We believe that including condition- and procedure-specific payment measures will provide hospitals with actionable feedback that will better equip them to implement targeted improvements in comparison to an overall payment measure alone. Further, we believe that supplementing the MSPB measure with condition-specific and procedure-specific measures will provide both overall hospital-level and detailed information on high-cost and high-prevalence conditions and procedures to better inform their future spending plans. Moreover, the payment measures will help consumers and other payers and providers identify hospitals involved in the provision of efficient care for certain procedures.

The three procedures selected for the clinical episode-based payment measures were chosen based on the following criteria: (1) The condition constitutes a significant share of Medicare payments and potential savings for hospitalized patients during and surrounding a hospital stay; (2) there was a high degree of agreement among clinical experts consulted for this project that standardized Medicare payments for services provided during this episode can be linked to the care provided during the hospitalization; (3) episodes of care for the condition are comprised of a substantial proportion of payments and potential savings for post-acute care, indicating episode payment differences are driven by utilization outside of the MS–DRG payment; (4) episodes of care for the condition reflect high variation in post discharge payments, enabling differentiation among hospitals; and (5) the medical condition is managed by general medicine physicians or hospitalists and the surgical conditions are managed by surgical subspecialists, enabling comparison between similar practitioners. These selection criteria were also used for the three clinical episode-based payment measures finalized in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49664 through 49665).

The measures follow the general construction of episode-based measures previously adopted in the Hospital IQR Program: The NQF-endorsed MSPB measure finalized in the FY 2012 IPPS/LTCH PPS final rule for the Hospital IQR Program (76 FR 51626 through 74529); and the three clinical episode-based payment measures for kidney/UTI, cellulitis, and gastrointestinal hemorrhage finalized in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49674). Similar to these previously adopted measures, the proposed measures include standardized payments for Medicare Part A and Part B services and are risk adjusted for individual patient characteristics and other factors (for example, the MS–DRG of the index inpatient stay). However, unlike the MSPB measure, the clinical episode-based payment measures only include Medicare Part A and Part B services that are clinically related to the named episode procedure. The clinical episode-based payment measures are price-standardized, risk-adjusted ratios that compare a provider's resource use against the resource use of other providers within a reporting period (that is, the measure calculation includes eligible episodes occurring within a 1-year timeframe). Similar to the MSPB measure though, the ratio allows for ease of comparison over time as it obviates the need to adjust for inflation.

Each clinical episode-based payment measure is calculated as the ratio of the Episode Amount for each provider divided by the episode-weighted median Episode Amount across all providers. To calculate the Episode

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[95] MSPB measure specifications can be found in the "Medicare Spending Per Beneficiary (MSPB) Measure Overview," available at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996.*

[96] Spreadsheet of MAP 2016 Final Recommendations. Available at: *http://www.qualityforum.org/map/.*

Amount for each provider, one calculates the average of the ratio of the observed episode payment over the expected episode payment (as predicted in risk adjustment), and then multiplies this quantity by the average observed episode payment level across all providers nationally. The denominator for a provider's measure is the episode weighted national median[97] of Episode Amounts across all providers. A clinical episode-based payment measure of less than 1 indicates that a given provider's resource use is less than that of the national median provider during a reporting period. Mathematically, this is represented in equation (A) below.

$$\text{(A)}\ \mathit{Episode\ Measure}_j = \frac{\mathit{Episode\ Amount}_j}{\begin{array}{c}\mathit{Episode{-}Weighted}\\ \mathit{Median\ of\ All\ Providers'}\\ \mathit{Episode\ Amounts}\end{array}} = \frac{\dfrac{\Sigma_{i\in j}(\frac{O_{ij}}{E_{ij}})}{n_j} * \bar{O}_{i\in I}}{\begin{array}{c}\mathit{Episode{-}Weighted}\\ \mathit{Median\ of\ All\ Providers'}\\ \mathit{Episode\ Amounts}\end{array}}$$

Where:

O_{ij} = observed episode payment for episode i in provider j,

E_{ij} = expected episode payment for episode i in provider j,

$\bar{O}_{i\in I}$ = average observed episode payment across all episodes i nationally, and

n_j = total number of episodes for provider j.

Each of the three measures we are proposing is described further below, followed by explanations of payment standardization and risk adjustment. For detailed measure specifications, we refer readers to the clinical episode-based payment measures report entitled, "Measure Specifications: Hospital Clinical Episode-Based Payment Measures for Aortic Aneurysm Procedure, Cholecystectomy and Common Duct Exploration, and Spinal Fusion" available at: *http://www.qualitynet.org* > Hospital-Inpatient > Claims-Based Measures > Episode-Based Payment Measures.

(2) Proposed Aortic Aneurysm Procedure Clinical Episode-Based Payment (AA Payment) Measure

(a) Background

Inpatient hospital stays and associated services assessed by the proposed Aortic Aneurysm Procedure Clinical Episode-Based Payment (AA Payment) measure have high payments with substantial variation. In CY 2014, Medicare FFS beneficiaries experienced more than 22,000 aortic aneurysm procedure episodes triggered by related inpatient stays. Payment-standardized, risk-adjusted episode payment for these episodes (payment for the hospitalization plus payment for clinically related services in the episode window) totaled nearly $760 million in CY 2014, with a mean episode payment of over $33,000. There is substantial variation in aortic aneurysm procedure episode payment—ranging from approximately $21,000 at the 5th percentile to approximately $62,000 at the 95th percentile—that is partially driven by variation in postdischarge payment clinically-related to the inpatient hospitalization.[98] These clinically-related postdischarge payments may be an indicator of the quality of care provided during the hospitalization. Specifically, higher quality hospital treatment may yield lower postdischarge payment.

(b) Overview of Measure

The proposed AA Payment measure includes the set of medical services related to a hospital admission for an aortic aneurysm procedure, including treatment, follow-up, and postacute care. The measure includes two clinical subtypes: (1) Abdominal Aortic Aneurysm Procedure; and (2) Thoracic Aortic Aneurysm Procedure. Clinical subtypes are included in the measure construction to distinguish relatively homogeneous subpopulations of patients whose health conditions significantly influence the form of treatment and the expected post-discharge outcomes and risks. The risk adjustment model is estimated separately for each clinical subtype, such that the measure compares observed spending for an episode of a given clinical subtype only to expected spending among episodes of that subtype. This measure, like the NQF-endorsed MSPB measure (NQF #2158), assesses the payment for services initiated during an episode that spans the period immediately prior to, during, and following a beneficiary's hospital stay (the "episode window", discussed in more detail below). In contrast to the MSPB measure, however, this proposed measure includes Medicare payments for services during the episode window only if they are clinically related to the aortic aneurysm procedure that was performed during the index hospital stay.

(c) Data Sources

The proposed AA Payment measure is a claims-based measure. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized for an aortic aneurysm procedure. The reporting period for the measure is 1 year (that is, the measure calculation includes eligible episodes occurring within a 1-year timeframe). For example, for the FY 2019 payment determination, the reporting period would be CY 2017.

(d) Measure Calculation

The proposed AA Payment measure sums the Medicare payment amounts for clinically related Part A and Part B services provided during the episode window and attributes them to the hospital at which the index hospital stay occurred. Medicare payments included in this episode-based measure are standardized and risk-adjusted. Similar to the MSPB measure's construction, this measure is expressed as a risk-adjusted ratio, which allows for ease of comparison over time, without the need to adjust for inflation. The numerator is the Episode Amount, calculated as the average of the ratios of the observed episode payment over the expected episode payment (as predicted in risk adjustment), multiplied by the average observed episode payment level across all providers nationally. The denominator for a provider's measure is the episode weighted national median of Episode Amounts across all providers. An aortic aneurysm procedure episode begins 3 days prior to the initial (index) admission and extends 30 days following the discharge from the index hospital stay. For detailed measure specifications, we refer readers to the clinical episode-based payment measures report entitled, "Measure Specifications: Hospital Clinical Episode-Based Payment Measures for Aortic Aneurysm Procedure, Cholecystectomy and Common Duct Exploration, and Spinal Fusion" and available at: *http://www.qualitynet.org* > Hospital-Inpatient > Claims-Based Measures > Episode-Based Payment Measures.

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[97] Example of episode weighted median: If there are 2 hospitals and one hospital had an measure score of 1.5 and another had one of 0.5, but the first had 4 episodes and the second only 1, then the episode-weighted median would be 1.5 (that is, 0.5, 1.5, 1.5, 1.5, 1.5).

[98] Statistics based on Acumen's testing of episode definition on Medicare FFS population using Medicare Parts A and B claims.

(e) Cohort

The proposed AA Payment measure cohort includes Medicare FFS beneficiaries hospitalized for an aortic aneurysm procedure. Measure exclusions are discussed in more detail in section VIII.A.7.a.(5) of the preamble of this proposed rule.

We are inviting public comment on our proposal to adopt the Aortic Aneurysm Procedure Clinical Episode-Based Payment (AA Payment) measure to the Hospital IQR Program measure set for the FY 2019 payment determination and subsequent years as discussed in this section.

(3) Proposed Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment (Chole and CDE Payment) Measure

(a) Background

Inpatient hospital stays and associated services assessed by the proposed Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment (Chole and CDE Payment) measure have high payments with substantial variation. In CY 2014, Medicare FFS beneficiaries experienced more than 48,000 cholecystectomy and common duct exploration episodes triggered by related inpatient stays. Payment-standardized, risk-adjusted episode payment for these episodes (payment for the hospitalization plus the payment for clinically related services in the episode window) totaled nearly $690 million in CY 2014, with a mean episode payment of over $14,000. There is substantial variation in cholecystectomy and common duct exploration episode payment—ranging from approximately $11,000 at the 5th percentile to approximately $22,000 at the 95th percentile—that is partially driven by variation in postdischarge payment clinically-related to the inpatient hospitalization.[99] These clinically-related postdischarge payments may be an indicator of the quality of care provided during the hospitalization. Specifically, higher quality hospital treatment may yield lower postdischarge payment.

(b) Overview of Measure

The proposed Chole and CDE Payment measure includes the set of medical services related to a hospital admission for a cholecystectomy and common duct exploration, including treatment, follow-up, and postacute care. This measure, like the NQF-endorsed MSPB measure (NQF #2158), assesses the payment for services initiated during an episode that spans the period immediately prior to, during, and following a beneficiary's hospital stay (the "episode window", discussed in more detail below). In contrast to the MSPB measure, however, this measure includes Medicare payments for services during the episode window only if they are clinically related to the cholecystectomy and common duct exploration that was performed during the index hospital stay.

(c) Data Sources

The proposed Chole and CDE Payment measure is a claims-based measure. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized for a cholecystectomy and common duct exploration. The reporting period for the measure is 1 year (that is, the measure calculation includes eligible episodes occurring within a 1-year timeframe). For example, for the FY 2019 payment determination, the reporting period would be CY 2017.

(d) Measure Calculation

The proposed Chole and CDE Payment measure sums the Medicare payment amounts for clinically related Part A and Part B services provided during the episode window and attributes them to the hospital at which the index hospital stay occurred. Medicare payments included in this episode-based measure are standardized and risk-adjusted. Similar to the MSPB measure's construction, this measure is expressed as a risk-adjusted ratio, which allows for ease of comparison over time, without need to adjust for inflation. The numerator is the Episode Amount, calculated as the average of the ratios of the observed episode payment over the expected episode payment (as predicted in risk adjustment), multiplied by the average observed episode payment level across all providers nationally. The denominator for a provider's measure is the episode weighted national median of Episode Amounts across all providers. A cholecystectomy and common duct exploration episode begins 3 days prior to the initial (index) admission and extends 30 days following the discharge from the index hospital stay. For detailed measure specifications, we refer readers to the clinical episode-based payment measures report entitled, "Measure Specifications: Hospital Clinical Episode-Based Payment Measures for Aortic Aneurysm Procedure, Cholecystectomy and Common Duct Exploration, and Spinal Fusion" and available at: *http://www.qualitynet.org* > Hospital-Inpatient > Claims-Based Measures > Episode-Based Payment Measures.

(e) Cohort

The proposed Chole and CDE Payment measure cohort includes Medicare FFS beneficiaries hospitalized for cholecystectomy and common duct exploration. Measure exclusions are discussed in more detail in section VIII.A.7.a.(5) of the preamble of this proposed rule below.

We are inviting public comment on our proposal to adopt the Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment (Chole and CDE Payment) measure to the Hospital IQR Program measure set for the FY 2019 payment determination and subsequent years as discussed in this section.

(4) Proposed Spinal Fusion Clinical Episode-Based Payment (SFusion Payment) Measure

(a) Background

Inpatient hospital stays and associated services assessed by the proposed Spinal Fusion Clinical Episode-Based Payment (SFusion Payment) measure have high payments with substantial variation. In CY 2014, Medicare FFS beneficiaries experienced nearly 60,000 spinal fusion episodes triggered by related inpatient stays. Payment-standardized, risk-adjusted episode payment for these episodes (payment for the hospitalization plus the payment for clinically related services in the episode window) totaled over $2 billion in CY 2014, with a mean episode payment of over $35,000. There is substantial variation in spinal fusion episode payment—ranging from approximately $27,000 at the 5th percentile to approximately $56,000 at the 95th percentile—that is partially driven by variation in postdischarge payment clinically-related to the inpatient hospitalization.[100] These clinically-related postdischarge payments may be an indicator of the quality of care provided during the hospitalization. Specifically, higher quality hospital treatment may yield lower postdischarge payment.

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[99] Statistics based on Acumen's testing of episode definition on Medicare FFS population using Medicare Parts A and B claims.

[100] Statistics based on Acumen's testing of episode definition on Medicare FFS population using Medicare Parts A and B claims.

(b) Overview of Measure

The proposed SFusion Payment measure includes the set of medical services related to a hospital admission for a spinal fusion, including treatment, follow-up, and postacute care. The measure includes five clinical subtypes: (1) Anterior Fusion—Single; (2) Anterior Fusion—2 Levels; (3) Posterior/Posterior-Lateral Approach Fusion—Single; (4) Posterior/Posterior-Lateral Approach Fusion—2 or 3 Levels; and (5) Combined Fusions. The clinical subtypes are included in the measure construction to distinguish relatively homogeneous subpopulations of patients whose health conditions significantly influence the form of treatment and the expected outcomes and risks. The risk adjustment model is estimated separately for each clinical subtype, such that the measure compares observed spending for an episode of a given clinical subtype only to expected spending among episodes of that subtype. A similar measure, the Lumbar Spinal Fusion/Refusion Clinical Episode-Based Payment Measure, was proposed for inclusion in the Hospital IQR Program in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24570–24571). Based on public comment regarding the heterogeneity of the spinal fusion patient population, we decided not to finalize the measure for the Hospital IQR Program at that time (80 FR 49668 through 49674). We have since refined the measure by including more granular subtypes of fusions of the lumbar spine to create more homogenous patient cohorts.

This proposed measure, like the NQF-endorsed MSPB measure (NQF #2158), assesses the payment for services initiated during an episode that spans the period immediately prior to, during, and following a beneficiary's hospital stay (the "episode window", discussed in more detail below). In contrast to the MSPB measure, however, this measure includes Medicare payments for services during the episode window only if they are clinically related to the spinal fusion procedure that was performed during the index hospital stay.

(c) Data Sources

The proposed SFusion Payment measure is a claims-based measure. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized for spinal fusion. The reporting period for the measure is 1 year (that is, the measure calculation includes eligible episodes occurring within a 1-year timeframe). For example, for the FY 2019 payment determination, the reporting period would be CY 2017.

(d) Measure Calculation

The proposed SFusion Payment measure sums the Medicare payment amounts for clinically related Part A and Part B services provided during the episode window and attributes them to the hospital at which the index hospital stay occurred. Medicare payments included in this episode-based measure are standardized and risk-adjusted. Similar to the MSPB measure's construction, this measure is expressed as a risk-adjusted ratio, which allows for ease of comparison over time, without need to adjust for inflation. The numerator is the Episode Amount, calculated as the average of the ratios of the observed episode payment over the expected episode payment (as predicted in risk adjustment), multiplied by the average observed episode payment level across all providers nationally. The denominator for a provider's measure is the episode weighted national median of Episode Amounts across all providers. A spinal fusion episode begins 3 days prior to the initial (index) admission and extends 30 days following the discharge from the index hospital stay.

For detailed measure specifications, we refer readers to the clinical episode-based payment measures report entitled, "Measure Specifications: Hospital Clinical Episode-Based Payment Measures for Aortic Aneurysm Procedure, Cholecystectomy and Common Duct Exploration, and Spinal Fusion" available at: *http://www.qualitynet.org* > Hospital-Inpatient > Claims-Based Measures > Episode-Based Payment Measures.

(e) Cohort

The proposed SFusion Payment measure cohort includes Medicare FFS beneficiaries hospitalized for spinal fusion. Measure exclusions are discussed in more detail in section VIII.A.7.a.(5) of the preamble of this proposed rule below.

We are inviting public comment on our proposal to adopt the Spinal Fusion Clinical Episode-Based Payment (SFusion Payment) measure to the Hospital IQR Program measure set for the FY 2019 payment determination and subsequent years as discussed in this section.

(5) Exclusion Criteria

For a full list of the MS–DRG, procedure, and diagnosis codes used to identify beneficiaries included in the final cohort for each of the proposed episode-based payment measures, we refer readers to the report entitled, "Measure Specifications: Hospital Clinical Episode-Based Payment Measures for Aortic Aneurysm Procedure, Cholecystectomy and Common Duct Exploration, and Spinal Fusion" available at: *http://www.qualitynet.org* > Hospital-Inpatient > Claims-Based Measures > Episode-Based Payment Measures.

Episodes for beneficiaries that meet any of the following criteria are excluded from all three measures: (1) Lack of continuous enrollment in Medicare Part A and Part B from 90 days prior to the episode through the end of the episode with traditional Medicare fee-for-service as the primary payer; (2) Death date during episode window; or (3) Enrollment in Medicare Advantage anytime from 90 days prior to the episode through the end of the episode.

In addition, claims that meet any of the following criteria do not trigger, or open, an episode for all three measures: (1) Claims with data coding errors, including missing date of birth or death dates preceding the date of the trigger event; (2) Claims with standardized payment ≤ 0; (3) Admissions to hospitals that Medicare does not reimburse through the IPPS system (for example, cancer hospitals, critical access hospitals, hospitals in Maryland); or (4) Transfers (by which a transfer is defined based on the claim discharge code) are not considered index admissions. In other words, these cases do not generate new episodes; neither the hospital that transfers a patient to another hospital, nor the receiving hospital will have an index admission or associated admission attributed to them.

(6) Standardization

Standardization, or payment standardization, is the process of adjusting the allowed charge for a Medicare service to facilitate comparisons of resource use across geographic areas. Medicare payments included in these proposed episode-based measures would be standardized according to the standardization methodology previously finalized for the MSPB measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51627). The methodology removes geographic payment differences, such as wage index and geographic practice cost index, incentive payment adjustments, and other add-on payments that support broader Medicare program goals, such as add-on payments for indirect graduate medical education (IME) and add-ons for serving a disproportionate share of uninsured patients.[101]

(7) Risk Adjustment

Risk adjustment uses patient claims history to account for case-mix variation and other factors. The steps used to calculate risk-adjusted payments align with the NQF-endorsed MSPB measure (NQF #2158) method as specified in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51624 through 51626). For more details on the specifications for the risk adjustment employed in the proposed episode-based payment measures, we refer readers to the report entitled, "Measure Specifications: Hospital Clinical Episode-Based Payment Measures for Aortic Aneurysm Procedure, Cholecystectomy and Common Duct Exploration, and Spinal Fusion" available at: *http://www.qualitynet.org* > Hospital-Inpatient > Claims-Based Measures > Episode-Based Payment Measures.

We are inviting public comment on our proposals to add three clinical episode-based payment measures as stated above for the FY 2019 payment determination and subsequent years.

b. Proposed Adoption of Excess Days in Acute Care After Hospitalization for Pneumonia (PN Excess Days) Measure

(1) Background

Pneumonia is a priority area for outcomes measurement because it is a common condition associated with considerable morbidity, mortality, and healthcare spending. Pneumonia was the third most common principal discharge diagnosis among patients with Medicare in 2011.[102] Pneumonia also accounts for a large fraction of hospitalization costs, and it was the seventh most expensive condition billed to Medicare, accounting for 3.7 percent of the total national costs for all Medicare hospitalizations in 2011.[103]

Some of the costs for pneumonia can be attributed to high acute care utilization for post-discharge pneumonia patients in the form of readmissions, observation stays, and emergency department (ED) visits. Patients admitted for pneumonia have disproportionately high readmission rates, and that readmission rates following discharge for pneumonia are highly variable across hospitals in the United States.[104] [105]

For the previously adopted Hospital IQR Program measure, Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization (NQF #0506) (hereinafter referred to as READM–30–PN) (80 FR 49654 through 49660), publicly reported 30-day risk-standardized readmission rates for pneumonia ranged from 12.9 percent to 24.8 percent for the time period between July 2012 and June 2015.[106] However, during the post-discharge period, patients are not only at risk of requiring readmission. Emergency Department (ED) visits represent a significant proportion of post-discharge acute care utilization. Two recent studies conducted in patients of all ages have shown that 9.5 percent of patients return to the ED within 30 days of hospital discharge and approximately 12 percent of these patients are discharged from the ED, and thus are not captured by the READM–30–PN Measure.[107] [108]

In addition, over the past decade, the use of observation stays has rapidly increased. Specifically, between 2001 and 2008, the use of observation services increased nearly three-fold,[109] and significant variation has been demonstrated in the use of observation services.

Thus, in the context of the previously adopted and publicly reported READM–30–PN measure, the increasing use of ED visits and observation stays has raised concerns that the READM–30–PN measure does not capture the full range of unplanned acute care in the post-discharge period. In particular, some policymakers and stakeholders have expressed concern that high use of observation stays in some cases could replace readmissions, and hospitals with high rates of observation stays in the post-discharge period may therefore have low readmission rates that do not more fully reflect the quality of care.[110]

In response to these concerns, we improved on a previously developed measure, which is not currently part of the Hospital IQR Program measure set, titled, "30-Day Post-Hospital Pneumonia Discharge Care Transition Composite" (NQF #0707—NQF endorsement removed). The improved measure entitled Excess Days in Acute Care after Hospitalization for Pneumonia (PN Excess Days) is a risk-adjusted outcome measure for pneumonia that incorporates the full range of acute care use that patients may experience post-discharge: Hospital readmissions, observation stays, and ED visits. We are proposing this PN Excess Days measure for inclusion in the Hospital IQR Program for the FY 2019 payment determination and subsequent years.

The proposed PN Excess Days measure assesses all-cause acute care utilization for post-discharge pneumonia patients for several reasons. First, from the patient perspective, acute care utilization for any cause is undesirable. It is costly, exposes patients to additional risks of medical care, interferes with work and family care, and imposes significant burden on caregivers. Second, limiting the measure to inpatient utilization may make it susceptible to gaming. Finally, this measure includes all-cause acute care utilization because it is often hard to exclude quality concerns and accountability based on the documented cause of a hospital visit.

Although the original measure was NQF-endorsed, this improved measure has not yet been NQF-endorsed. Section 1886(b)(3)(B)(IX)(bb) of the Act provides that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. While we considered other existing measures related to care transitions and post-discharge acute care utilization that have been endorsed by NQF or other consensus organizations, but we were unable to identify any NQF-endorsed (or other consensus organization endorsed) measures that assess the full range of post-discharge acute care use that patients may experience. Existing process measures capture many important domains of care transitions such as education, medication reconciliation, and follow-up, but all require chart review and manual abstraction. Existing outcome measures are focused entirely on readmissions or complications and do not include observation stays or ED visits. We are not aware of any other measures that assess the quality of transitional care by measuring 30-day risk-standardized days in acute care (hospital readmissions, observation stays, and ED visits) following hospitalization for pneumonia that have been endorsed or adopted by a consensus organization, and we have not found any other feasible and practical measures on this topic. However, we note that this measure has been submitted to NQF for endorsement proceedings as part of the All-Cause Admissions and Readmissions project in January 2016.

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[101] An overview of payment standardization can be found in the "CMS Price (Payment) Standardization—Basics" document available at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPages%2FQnetTier4&cid=1228772057350.*

[102] Agency for Healthcare Research and Quality (AHRQ). *Healthcare Cost and Utilization Project (HCUP) http://hcupnet.ahrq.gov/.*

[103] Torio CM, Andrews RM. National Inpatient Hospital Costs: The Most Expensive Conditions by Payer, 2011. HCUP Statistical Brief #160. 2013; *http://hcup-us.ahrq.gov/reports/statbriefs/sb160.jsp.*

[104] Lindenauer PK, Bernheim SM, Grady JN, et al. The performance of US hospitals as reflected in risk-standardized 30-day mortality and readmission rates for medicare beneficiaries with pneumonia. *J Hosp Med.* 2010;5(6):E12–18.

[105] Dharmarajan K, Hsieh AF, Lin Z, et al. Hospital readmission performance and patterns of readmission: retrospective cohort study of Medicare admissions. *BMJ.* 2013;347:f6571.

[106] Dorsey K, Grady J, Desai N, Lindenauer P, et al. 2016 Condition-Specific Measures Updates and Specifications Report: Hospital-Level Risk-Standardized Readmission Measures for Acute Myocardial Infarction, Heart Failure, and Pneumonia. 2016.

[107] Rising KL, White LF, Fernandez WG, Boutwell AE.: Emergency Department Visits After Hospital Discharge: A Missing Part of the Equation. *Annals of Emergency Medicine.* 2013(0).

[108] Vashi AA, Fox JP, Carr BG, et al.: Use of hospital-based acute care among patients recently discharged from the hospital. *JAMA: the journal of the American Medical Association.* Jan 23 2013;309(4):364–371.

[109] Venkatesh AK GB, Gibson Chambers JJ, Baugh CW, Bohan JS, Schuur JD. Use of Observation Care in US Emergency Departments, 2001 to 2008. *PLoS One.* September 2011;6(9):e24326.

[110] Carlson J. Readmissions are down, but observational-status patients are up and that could skew Medicare numbers. Modern Healthcare. 2013.

The proposed PN Excess Days measure was developed in conjunction with the previously adopted Hospital IQR Program measures, Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction (AMI Excess Days) (80 FR 49690) and Hospital 30-Day Excess Days in Acute Care after Hospitalization for Heart Failure (HF Excess Days) (80 FR 49690). All three measures assess the same outcome and use the same risk-adjustment methodology. They differ only in the target population and the specific risk variables included.

When we finalized the AMI Excess Days and HF Excess Days measures for the FY 2018 payment determination and subsequent years, stakeholders expressed concern about the interaction between Medicare payment policy regarding admissions spanning two midnights and the AMI Excess Days and HF Excess Days measures (80 FR 49686 through 49687). We continue to believe that the "2-midnight" policy or any changes to such policy will not influence the outcome of Excess Days in Acute Care measures, as all postdischarge days in acute care are captured whether they are billed as inpatient or outpatient days (80 FR 49686 through 49687).

The proposed PN Excess Days measure (MUC15–391) was included on a publicly available document entitled "2015 Measures Under Consideration List" for December 1, 2015 (available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*) and has been reviewed by the NQF Measure Applications Partnership (MAP) Hospital Workgroup. The measure was conditionally supported pending the examination of sociodemographic status (SDS) factors and NQF review and endorsement of the measure update, as referenced in the MAP 2016 Final Recommendations Report (available at: *http://www.qualityforum.org/map/*).[111] We refer readers to section VIII.A.6.a.(1) of the preamble of this proposed rule for a discussion of our policy on SDS factors. As stated above, we note that this measure has been submitted to NQF for endorsement proceedings as part of the All-Cause Admissions and Readmissions project in January 2016.

(2) Overview of Measure

The proposed PN Excess Days measure is a risk-standardized outcome measure that compares the number of days that patients, discharged from a hospital for pneumonia, are predicted to spend in acute care across the full spectrum of possible events (hospital readmissions, observation stays, and ED visits) to the days that patients are expected to spend based on their degree of illness as defined using principal diagnosis and comorbidity data from administrative claims.

(3) Data Sources

The proposed PN Excess Days measure is claims-based. It uses Part A and Part B Medicare administrative claims data from Medicare FFS beneficiaries hospitalized for pneumonia. To determine eligibility for inclusion in the measure, we also use Medicare enrollment data. As proposed, the measure would use 3 years of data. For example, for the FY 2019 payment determination, the reporting period would be July 2014 through June 2017.

(4) Outcome

The outcome of the proposed PN Excess Days measure is the excess number of days patients spend in acute care (hospital readmissions, observation stays, and ED visits) per 100 discharges during the first 30 days after discharge from the hospital, relative to the number spent by the same patients discharged from an average hospital. The measure defines days in acute care as days spent: (1) In an ED; (2) admitted to observation status; or (3) admitted as an unplanned readmission for any cause within 30 days from the date of discharge from the index pneumonia hospitalization. Readmission days are calculated as the discharge date minus the admission date. Admissions that extend beyond the 30-day follow-up period are truncated on day 30. Observation days are calculated by the hours in observation, rounded up to the nearest half day. Based on the recommendation of our technical expert panel convened as part of developing this measure, an ED treat-and-release visit is counted as one half day. ED visits are not counted as a full day because the majority of treat-and-release visits last fewer than 12 hours.

"Planned" readmissions are those planned by providers for anticipated medical treatment or procedures that must be provided in the inpatient setting. This measure excludes planned readmissions using the planned readmission algorithm previously developed for the READM–30–PN measure (78 FR 50786 through 50787). The planned readmission algorithm is a set of criteria for classifying admissions as planned among the general Medicare population using Medicare administrative claims data. The algorithm identifies admissions that are typically planned and may occur within 30 days of discharge from the hospital. The planned readmission algorithm has three fundamental principles: (1) A few specific, limited types of care are always considered planned (transplant surgery, maintenance chemotherapy/immunotherapy, rehabilitation); (2) otherwise, a planned readmission is defined as a non-acute readmission for a scheduled procedure; and (3) admissions for acute illness or for complications of care are never planned. A more detailed discussion of exclusions follows in section VIII.A.7.b.(6) of the preamble of this proposed rule.

The measure counts all use of acute care occurring in the 30-day post-discharge period. For example, if a patient returns to the ED three times, the measure counts each ED visit as a half-day. Similarly, if a patient has two hospitalizations within 30 days, the days spent in each are counted. We take this approach to capture the full patient experience of need for acute care in the post-discharge period.

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[111] Spreadsheet of MAP 2016 Final Recommendations Available at: *http://www.qualityforum.org/map/*.

(5) Cohort

We defined the eligible cohort using the same criteria as the previously adopted Hospital IQR Program measure, READM–30–PN (80 FR 49654 through 49660). The READM–30–PN cohort criteria are included in a report posted on our Measure Methodology Web page, under the "Downloads" section in the "AMI, HF, PN, COPD, and Stroke Readmission Updates" zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

The cohort includes Medicare FFS patients aged 65 years or older: (1) With a principal discharge diagnosis of pneumonia, a principal discharge diagnosis of aspiration pneumonia, or a principal discharge diagnosis of sepsis (not including severe sepsis) who also have a secondary diagnosis of pneumonia present on admission; (2) enrolled in Part A and Part B Medicare for the 12 months prior to the date of admission, and enrolled in Part A during the index admission; (3) who were discharged from a non-Federal acute care hospital; (4) who were not transferred to another acute care facility; and (5) who were alive at discharge.

The measure cohort is also harmonized with the previously adopted Hospital IQR Program measure, the MORT–30–PN measure (80 FR 49837), and the proposed refined cohort for the PN Payment measure proposed in section VIII.A.6.a. of the preamble of this proposed rule.

For the ICD–9–CM and ICD–10–CM codes that define the measure development cohort, we refer readers to the "Excess Days in Acute Care after Hospitalization for Pneumonia Version 1.0" in the Pneumonia Excess Days in Acute Care zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

(6) Exclusion Criteria

The proposed PN Excess Days measure excludes the following admissions from the measure cohort: (1) Hospitalizations without at least 30 days of post-discharge enrollment in Part A and Part B FFS Medicare, because the 30-day outcome cannot be assessed in this group since claims data are used to determine whether a patient was readmitted, was placed under observation, or visited the ED; (2) discharged against medical advice, because providers did not have the opportunity to deliver full care and prepare the patient for discharge; and (3) hospitalizations for patients with an index admission within 30 days of a previous index admission, because additional pneumonia admissions within 30 days are part of the outcome, and we choose not to count a single admission both as an index admission and a readmission for another index admission.

(7) Risk-Adjustment

The proposed PN Excess Days measure adjusts for variables that are clinically relevant and have strong relationships with the outcome. The measure seeks to adjust for case-mix differences among hospitals based on the clinical status of the patient at the time of the index admission. Accordingly, only comorbidities that convey information about the patient at that time or in the 12 months prior, and not complications that arise during the course of the index hospitalization, are included in the risk adjustment. The measure does not adjust for patients' admission source or their discharge disposition (for example, skilled nursing facility) because these factors are associated with the structure of the healthcare system, not solely patients' clinical comorbidities. Patients' admission source and discharge disposition may be influenced by regional differences in the availability of post-acute care providers and practice patterns. These regional differences might exert undue influence on results. In addition, patients' admission source and discharge disposition are not audited and are not as reliable as diagnosis codes. The proposed PN Excess Days measure uses the same risk-adjustment variables as the READM–30–PN (73 FR 48614).

The outcome is risk adjusted using a two-part random effects model. This statistical model, often referred to as a "hurdle" model, accounts for the structure of the data (patients clustered within hospitals) and the observed distribution of the outcome. Specifically, it models the number of acute care days for each patient as: (1) a probability that they have a non-zero number of days; and (2) a number of days, given that this number is non-zero. The first part is specified as a logit model, and the second part is specified as a Poisson model, with both parts having the same risk-adjustment variables and each part having a random effect. This is an accepted statistical method that explicitly estimates how much of the variation in acute care days is accounted for by patient risk factors, how much by the hospital where the patient is treated, and how much is explained by neither. This model is used to calculate the predicted (including random effects) and expected (assuming random effects are zero) number of days for each patient. The average difference between the predicted and expected number of days for each patient for each hospital is used to construct the risk-standardized Excess Days in Acute Care. For more details about risk-adjustment for this proposed measure, we refer readers to the "Pneumonia Excess Days in Acute Care" zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

(8) Calculating Excess Acute Care Days

The proposed PN Excess Days measure is calculated as the difference between the average of the predicted number of days spent in acute care for patients discharged from each hospital and the average number of days that would have been expected if those patients had been cared for at an average hospital, and then the difference is multiplied by 100 so that the measure result represents PN Excess Days per 100 discharges. We multiply the final measure by 100 to be consistent with the reporting of the previously adopted READM–30–PN measure that is reported as a rate (that is, a 25 percent rate is equivalent to 25 out of 100 discharges) (80 FR 49654 through 49660), as well as the AMI Excess Days (80 FR 49690) and HF Excess Days (80 FR 49685) measures. A positive result indicates that patients spend more days in acute care post-discharge than expected if admitted to an average performing hospital with a similar case mix; a negative result indicates that patients spend fewer days in acute care than expected if admitted to an average performing hospital with a similar case mix. A negative PN Excess Days measure score reflects better quality.

We are inviting public comment on our proposal to adopt the PN Excess Days measure for the FY 2019 payment determination and subsequent years as described above.

c. Summary of Previously Adopted and Newly Proposed Hospital IQR Program Measures for the FY 2019 Payment Determination and Subsequent Years

The table below outlines the proposed Hospital IQR Program measure set for the FY 2019 payment determination and subsequent years, and includes both previously adopted measures and measures newly proposed in this proposed rule. Measures proposed for removal in section VIII.A.3.b. of the preamble of this proposed rule are not included in this chart.

PROPOSED HOSPITAL IQR PROGRAM MEASURE SET FOR THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Short name	Measure name	NQF No.
	NHSN	
CAUTI	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	1717
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI.	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
HCP	Influenza Vaccination Coverage Among Healthcare Personnel	0431
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	1716
	Chart-abstracted	
ED–1 *	Median Time from ED Arrival to ED Departure for Admitted ED Patients	0495
ED–2 *	Admit Decision Time to ED Departure Time for Admitted Patients	0497
Imm-2	Influenza Immunization	1659
PC–01 *	Elective Delivery (Collected in aggregate, submitted via Web-based tool or electronic clinical quality measure).	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
VTE–6	Incidence of Potentially Preventable Venous Thromboembolism	+
	Claims-based Outcome	
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0230
MORT–30–CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery.	2558
MORT–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1893
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization.	0229
MORT–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.	0468
MORT–30–STK	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Ischemic Stroke	N/A
READM–30–AMI	Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization.	0505
READM–30–CABG	Hospital 30-Day, All-Cause, Unplanned, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery.	2515
READM–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1891
READM–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure (HF) Hospitalization.	0330
READM–30–HWR	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
READM–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization.	0506
READM–30–STK	30-Day Risk Standardized Readmission Rate Following Stroke Hospitalization	N/A
READM–30–THA/TKA	Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1551
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	N/A
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	N/A
PN Excess Days **	Excess Days in Acute Care after Hospitalization for Pneumonia	N/A
Hip/knee complications	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550
PSI 04	Death Rate among Surgical Inpatients with Serious Treatable Complications	0351
PSI 90	Patient Safety for Selected Indicators Composite Measure, Modified PSI 90 (Updated Title: Patient Safety and Adverse Events Composite).	0531
	Claims-based Payment	
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI).	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF).	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia.	2579

PROPOSED HOSPITAL IQR PROGRAM MEASURE SET FOR THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

Short name	Measure name	NQF No.
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty.	N/A
MSPB	Payment-Standardized Medicare Spending Per Beneficiary (MSPB)	2158
Cellulitis Payment	Cellulitis Clinical Episode-Based Payment Measure	N/A
GI Payment	Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure	N/A
Kidney/UTI Payment	Kidney/Urinary Tract Infection Clinical Episode-Based Payment Measure	N/A
AA Payment **	Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure	N/A
Chole and CDE Payment **	Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure	N/A
SFusion Payment **	Spinal Fusion Clinical Episode-Based Payment Measure	N/A
	Electronic Clinical Quality Measures (eCQMs)	
AMI–8a	Primary PCI Received Within 90 Minutes of Hospital Arrival	0163
CAC–3	Home Management Plan of Care Document Given to Patient/Caregiver	+
ED–1 *	Median Time from ED Arrival to ED Departure for Admitted ED Patients	0495
ED–2 *	Admit Decision Time to ED Departure Time for Admitted Patients	0497
EHDI–1a	Hearing Screening Prior to Hospital Discharge	1354
PC–01 *	Elective Delivery (Collected in aggregate, submitted via Web-based tool or electronic clinical quality measure).	0469
PC–05	Exclusive Breast Milk Feeding ***	0480
STK–02	Discharged on Antithrombotic Therapy	0435
STK–03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK–05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK–06	Discharged on Statin Medication	0439
STK–08	Stroke Education	+
STK–10	Assessed for Rehabilitation	0441
VTE–1	Venous Thromboembolism Prophylaxis	0371
VTE–2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
	Patient Survey	
HCAHPS	HCAHPS + 3-Item Care Transition Measure (CTM-3)	0166 0228
	Structural Measures	
Patient Safety Culture	Hospital Survey on Patient Safety Culture	N/A
Safe Surgery Checklist	Safe Surgery Checklist Use	N/A

* Measure listed twice, as both chart-abstracted and electronic clinical quality measure.

** Newly proposed measures for the FY 2019 payment determination and for subsequent years.

*** Measure name has been shortened. Please refer to annually updated electronically clinical quality measure specifications on the CMS eCQI Resource Center Page for further information: *https://www.healthit.gov/newsroom/ecqi-resource-center.*

+ NQF endorsement has been removed.

8. Proposed Changes to Policies on Reporting of eCQMs

For a discussion of our previously finalized eCQMs and policies, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50807 through 50810; 50811 through 50819), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50241 through 50253; 50256 through 50259; and 50273 through 50276), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49692 through 49698; and 49704 through 49709).

We are proposing two changes to our policies with respect to eCQMs reporting to require that hospitals: (1) Submit data for an increased number of eCQMs as further detailed below; and (2) report a full year of data. These proposals are made in conjunction with our proposals in section VIII.A.3.b.(3) of the preamble of this proposed rule to remove 13 eCQMs from the Hospital IQR Program and proposals in sections VIII.A.10.d. and VIII.E.2.b. of the preamble of this proposed rule to align requirements for the Hospital IQR and the Medicare and Medicaid EHR Incentive Programs.

In addition, we are clarifying that for three measures (ED–1, ED–2, and PC–01), our previously finalized policy that hospitals must submit a full year of chart-abstracted data regardless of whether data also are submitted electronically continues to apply.

a. Proposed Requirement That Hospitals Report on All eCQMs in the Hospital IQR Program Measure Set for the CY 2017 Reporting Period/FY 2019 Payment Determination and Subsequent Years

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49698), we finalized our policy to require hospitals to submit one quarter of data (either Q3 or Q4) for 4 self-selected eCQMs for the CY 2016 reporting period/FY 2018 payment determination by February 28, 2017. Furthermore, in that final rule (80 FR 49694), we signaled our intent to propose increasing the reporting requirement to 16 eCQMs in future rulemaking. In this proposed rule, we are proposing to require reporting of a full calendar year of data for all eCQMs in the Hospital IQR Program measure set for the CY 2017 reporting period/FY 2019 payment determination and subsequent years.

Requiring hospitals to electronically report a greater number of eCQMs furthers our goal of expanding electronic reporting in the Hospital IQR Program, which we believe will improve patient outcomes by providing more robust data to support quality improvement efforts. As stated above, this proposal is made in conjunction with our proposals in section VIII.A.3.b.(3) of the preamble of this proposed rule to remove thirteen eCQMs from the Hospital IQR Program and proposals in sections VIII.A.10.d. and VIII.E.2.b. of the preamble of this proposed rule to align requirements for the Hospital IQR and the Medicare and Medicaid EHR Incentive Programs. In addition, as discussed in section VIII.A.3.b.(3) of the preamble of this proposed rule, we believe that removing certain eCQMs for which the chart-abstracted versions have been determined to be "topped-out" will reduce certification burden and implementation hurdles, enabling hospitals to focus efforts on successfully implementing a smaller subset of eCQMs. If our proposals to remove 13 eCQMs in section VIII.A.3.b.(3) of the preamble of this proposed rule is finalized as proposed, hospitals would be required to report on a total 15 eCQMs for the CY 2017 reporting period/FY 2019 payment determination. While the number of required eCQMs would increase as compared to that required for the CY 2016 reporting period/FY 2018 payment determination (that is, from 4 to 15 eCQMs), we believe that a coordinated reduction in the overall number of eCQMs (from 28 to 15 eCQMs) in both the Hospital IQR and Medicare and Medicaid EHR Incentive Programs will reduce certification burden on hospitals and improve the quality of reported data by enabling hospitals to focus on a smaller, more specific subset of eCQMs.

In crafting this proposal, we also considered proposing to require a lesser number of eCQMs—that hospitals submit eight of the available eCQMs (that is, in other words, 8 of the proposed 15 eCQMs as discussed above) for the CY 2017 reporting period/FY 2019 payment determination. Specifically, hospitals would submit a full calendar year of data on an annual basis for eight of the available eCQMs whether reporting only for the Hospital IQR Program or if reporting for both the Medicare and Medicaid EHR Incentive Programs and the Hospital IQR Program for the CY 2017 reporting period/FY 2019 payment determination. Reporting on all eCQMs in the Hospital IQR Program measure set would begin with the CY 2018 reporting period/FY 2020 payment determination and subsequent years.

Ultimately we chose to propose to require reporting on all the proposed eCQMs for the CY 2017 reporting period/FY 2019 payment determination, because we believe that requiring hospitals to report measures electronically is in line with our goals to move towards eCQM reporting and to align with the Medicare and Medicaid EHR Incentive Programs. We believe that the CY 2017/FY 2019 payment determination is the appropriate time to require eCQM reporting because hospitals have had several years to report data electronically for the Medicare and Medicaid EHR Incentive Programs and Hospital IQR Program (3 years of voluntary reporting and 2 years of reporting as part of a pilot). Based upon data collected by CMS, currently, 95 percent of hospitals attest to successful eCQM reporting under the Medicare and Medicaid EHR Incentive Programs.

b. Proposed Requirement That Hospitals Report a Full Year of eCQM Data

In the FY 2016 IPPS/LTCH PPS final rule, we finalized our policy to require hospitals to submit one quarter of data (either Q3 or Q4) for 4 self-selected eCQMs for the CY 2016 reporting period/FY 2018 payment determination by February 28, 2017 (80 FR 49698). As previously stated, we believe that the CY 2017/FY 2019 payment determination is the appropriate time to require eCQM reporting because hospitals have had several years to report data electronically for the Medicare and Medicaid EHR Incentive Programs and for the Hospital IQR Program. As such, we are proposing that for the CY 2017 reporting period/FY 2019 payment determination and subsequent years, hospitals must submit one year's worth of eCQM data for each required eCQM. For example, for the ED–1 eCQM, hospitals would be required to submit one year of data (covering Q1, Q2, Q3, and Q4), instead of just one quarter of data (either Q3 or Q4) as previously required.

We hope to address stakeholder concerns associated with increasing the number of eCQMs for which reporting will be required proactively by reducing burden on hospitals by aligning data submission deadlines between the Hospital IQR Program and the Medicare EHR Incentive Program. We note that deadlines for the Medicaid EHR Incentive Program differ by State, and therefore our proposal to align data submission deadlines for eCQMs applies only to the Hospital IQR Program and the Medicare EHR Incentive Program and not to the Medicaid EHR Incentive Program. For more details on Hospital IQR Program reporting requirements and eCQM submission deadlines, we refer readers to section VIII.A.10.d.(5) of the preamble of this proposed rule.

c. Clarification Regarding Data Submission for ED–1, ED–2, PC–01, STK–4, VTE–5, and VTE–6

In the FY 2016 IPPS/LTCH PPS final rule, we finalized our policy that hospitals must continue to submit data on ED–1, ED–2, PC–01, STK–4, VTE–5, and VTE–6 via chart abstraction as previously required and that the results would be publicly displayed (80 FR 49695–49698). We also finalized, however, that hospitals may choose to submit electronic data on any of these 6 measures in addition to the chart-abstraction requirements to meet the requirement to report 4 of 28 eCQMs (80 FR 49695–49698). As discussed in section VIII.A.3.b.(3)(a)(ii) of the preamble of this proposed rule, we are proposing to remove the electronic version of the STK–4 measure. As discussed in section VIII.A.3.b.(3)(d) of the preamble of this proposed rule, we are proposing to remove the electronic version of the VTE–5 and VTE–6 measure. Lastly, in section VIII.A.3.b.(2) of the preamble of this proposed rule, we are proposing to remove the chart-abstracted versions of the STK–4 and VTE–5 measures. If these proposals are finalized as proposed, the STK–4 and VTE–5 measures will be completely removed from the Hospital IQR Program measure set, but the VTE–6 measure would continue to be included in its chart-abstracted form.

For the FY 2019 payment determination and subsequent years, we are clarifying that requirements for the chart-abstracted versions of ED–1, ED–2, PC–01, and VTE–6 remain the same as previously finalized. Hospitals must submit a full calendar year of data (covering Q1, Q2, Q3, and Q4) via chart-abstraction regardless of whether data also are submitted electronically in accordance with the applicable submission requirements. However, we note that if our proposal that hospitals submit a full calendar year of eCQM data for each required eCQM is finalized as proposed above, data submission for the chart-abstracted version of these measures will differ from those submitted electronically (quarterly basis for chart-abstracted measures versus annual basis for electronic measures).

We are inviting public comment on our proposals to require that hospitals: (1) Submit data for all eCQMs included in the Hospital IQR Program measure set; and (2) report a full year of data for the CY 2017 reporting period/FY 2019 payment determination and subsequent years, as discussed above.

9. Possible New Quality Measures and Measure Topics for Future Years

We are providing information about new quality measures and measure topics under consideration for future inclusion in the Hospital IQR Program. We are considering to propose in future rulemaking: (1) A refined version of the Stroke Scale for the Hospital 30-Day Mortality Following Acute Ischemic Stroke Hospitalization Measure; (2) a new measure, the National Healthcare Safety Network (NHSN) Antimicrobial Use Measure (NQF #2720); and (3) one or more potential measures of behavioral health for the inpatient hospital setting, including measures previously adopted for the IPFQR Program (80 FR 46694), for adoption into the Hospital IQR Program measure set. Also, we are considering public reporting of Hospital IQR Program data stratified by race, ethnicity, sex, and disability on *Hospital Compare.* These topics are further discussed below.

a. Potential Inclusion of the National Institutes of Health (NIH) Stroke Scale for the Hospital 30-Day Mortality Following Acute Ischemic Stroke Hospitalization Measure Beginning as Early as the FY 2022 Payment Determination

(1) Background

Mortality following stroke is an important adverse outcome that can be measured reliably and objectively and is influenced by the quality of care provided to patients during their initial hospitalization; therefore, mortality is an appropriate measure of quality of care following stroke hospitalization.[112][113] Specifically, post-stroke mortality rates have been shown to be influenced by critical aspects of care such as response to complications, speediness of delivery of care, organization of care, and appropriate imaging.[114][115][116][117] Therefore, we are refining the previously adopted CMS Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) following Acute Ischemic Stroke Hospitalization Measure (hereafter referred to as the Stroke 30-day Mortality Rate) (78 FR 50802) by changing the measure's risk adjustment to include stroke severity. We are considering proposing this refinement to the measure in the future.

The previously adopted Stroke 30-day Mortality Rate (78 FR 50802) includes 42 risk variables, but does not include an assessment of stroke severity. For more details on the measure as currently adopted and implemented, we refer readers to its measure methodology report and measure risk-adjustment statistical model in the AMI, HF, PN, COPD, and Stroke Mortality Update zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

In the future, we are considering proposing a refinement to the Stroke 30-day Mortality Rate for several reasons. First, the refined measure would allow for more rigorous risk adjustment by incorporating the NIH Stroke Scale (discussed in more detail below) as an assessment of stroke severity.[118] Second, the inclusion of the NIH Stroke Scale is aligned with and supportive of clinical guidelines, as use of the NIH Stroke Scale to assess stroke severity upon acute ischemic stroke patient presentation is Class I recommended in the American Heart Association and American Stroke Association (AHA/ASA) guidelines.[119] Third, clinicians and stakeholders, including AHA, ASA, and other professional organizations, highlight the importance of including an assessment of stroke severity in risk-adjustment models of stroke mortality. Therefore, the refined Stroke 30-day Mortality Rate is responsive to comments received from the feedback of measure developers during measure development, the Technical Expert Panel, and the NQF endorsement process (78 FR 50802). Fourth, in addition to a modestly higher c-statistic, which evaluates the measure's ability to discriminate or differentiate between high and low performing hospitals, the refined Stroke 30-day Mortality Rate includes a more parsimonious risk model than the publicly reported stroke mortality measure, with a total of 20 risk adjustment variables including the NIH Stroke Scale, compared to the current use of 42 risk adjustment variables.

Initial stroke severity score, such as the NIH Stroke Scale score, is one of the strongest predictors of mortality in ischemic stroke patients,[120][121][122] and is part of the national guidelines on stroke care.[123] The NIH Stroke Scale is a 15-item neurologic examination stroke scale used to provide a quantitative measure of stroke-related neurologic deficit. The NIH Stroke Scale evaluates the effect of acute ischemic stroke on a patient's level of consciousness, language, neglect, visual-field loss, extra-ocular movement, motor strength, ataxia (the loss of full control of bodily movements), dysarthria (difficult or unclear articulation of speech), and sensory loss. The NIH Stroke Scale was designed to be a simple, valid, and reliable tool that can be administered at the bedside consistently by neurologists, physicians, nurses, or therapists. In October 2016, codes for the NIH Stroke Scale are expected to be added to the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD–10). The currently adopted measure covers 3 years of claims data using administrative claims from July 2011–June 2014. In order to give hospitals time to adjust to reporting the NIH Stroke Scale, we are considering this measure refinement for as early as the July 2017 through June 2020 reporting period (3 years of data), which would correspond to the FY 2022 payment determination in the Hospital IQR Program.

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[118] NIH Stroke Scale. Available at: *http://www.nihstrokescale.org/.*

[119] Jauch EC, Saver JL, Adams HP, Jr., et al. Guidelines for the early management of patients with acute ischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke.* Mar 2013;44(3):870–947.

[120] Fonarow GC, Saver JL, Smith EE, et al. Relationship of national institutes of health stroke scale to 30-day mortality in medicare beneficiaries with acute ischemic stroke. *J Am Heart Assoc.* Feb 2012;1(1):42–50.

[121] Nedeltchev K, Renz N, Karameshev A, et al. Predictors of early mortality after acute ischaemic stroke. *Swiss Medical Weekly.* 2010;140(17–18):254–259.

[122] Smith EE, Shobha N, Dai D, et al. Risk score for in-hospital ischemic stroke mortality derived and validated within the Get With the Guidelines-Stroke Program. *Circulation.* Oct 12 2010;122(15):149615041496–1504.

[123] Jauch EC, Saver JL, Adams HP, Jr., et al. Guidelines for the early management of patients with acute ischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke.* Mar 2013;44(3):870–947.

The measure refinement was developed in collaboration with the AHA/ASA. We sought to update the current publicly reported measure to include an assessment of stroke severity at this time, because it has become feasible to do so due to both the increased use of the NIH Stroke Scale related to the AHA/ASA guidelines that recommend administering the NIH Stroke Scale on all stroke patients, as well as due to the upcoming availability to obtain the scores through claims data (incorporation into ICD–10).

The Stroke 30-day Mortality Rate (MUC15–294) with the refined risk adjustment was included on a publicly available document entitled "List of Measures under Consideration for December 1, 2015" with identification number MUC15–294, (available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*) and has been reviewed by the MAP. The MAP conditionally supported this measure pending NQF review and endorsement and asked that CMS consider a phased approach in regards to implementation to avoid multiple versions of the same measure.[124] The MAP also noted that mortality is not the most meaningful outcome for stroke patients and to consider cognitive or functional outcomes such as impaired capacity.[125] The Stroke 30-day Mortality Rate with the refined risk adjustment was submitted to NQF for endorsement in the neurology project on January 15, 2016.

(2) Overview of Measure Change

The measure cohort for the refined measure would not be substantively different from the currently adopted, publicly reported Stroke 30-day Mortality Rate. In addition, the data sources, three-year reporting period, inclusion and exclusion criteria, as well as the assessment of the outcome of mortality would all align with the currently adopted measure.

(3) Risk Adjustment

The statistical modeling, measure calculation, and risk-adjustment calculation for this refined measure would align with the currently adopted Stroke 30-day Mortality Rate. However, we reselected risk variables, resulting in a final model with 20 risk-adjustment variables including the NIH Stroke Scale as an assessment of stroke severity. For the full measure specifications of the refined measure, we refer readers to the AMI, HF, PN, COPD, and Stroke Mortality Update zip file on our Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

In summary, we are considering proposing in the future a refinement of the Stroke 30-day Mortality Rate, which would change the risk adjustment to include an assessment of stroke severity, in the Hospital IQR Program for as early as the July 2017–June 2020 reporting period/FY 2022 payment determination and for subsequent years.

We are inviting comments on the possibility of a future proposal of refinements to the previously adopted Hospital 30-Day Mortality Following Acute Ischemic Stroke Hospitalization Measure to include the NIH Stroke Scale beginning as early as the FY 2022 payment determination.

b. Potential Inclusion of National Healthcare Safety Network (NHSN) Antimicrobial Use Measure (NQF #2720)

(1) Background

The emergence of antibiotic drug resistance is a clinical and public health problem that threatens the effective prevention and treatment of bacterial infections. The CDC estimates that each year at least two million people become infected with bacteria that are resistant to antibiotics, and at least 23,000 people die as a direct result of these drug-resistant bacterial infections. In addition, antibiotic resistance contributes an estimated $20 billion in excess direct healthcare costs.[126]

In order to promote the efficiency and coordination of efforts to detect, prevent, and control antibiotic resistance, HHS announced in 2015 the establishment of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (Advisory Council).[127] The Advisory Council makes recommendations to the Secretary regarding policies to support the implementation of the National Strategy for Combating Antibiotic-Resistant Bacteria [128] and the National Action Plan for Combating Antibiotic-Resistant Bacteria.[129] Evidence is accumulating that programs dedicated to optimizing inpatient antibiotic use, known as antimicrobial stewardship programs (ASPs), may slow the emergence of antibiotic resistance and improve appropriateness of antimicrobial use and patient outcomes.[130] [131] [132] Therefore, the CDC and several professional societies have published guidelines and resources to support hospitals in implementing antimicrobial stewardship programs.[133]

In the future, we are considering proposing the NHSN Antimicrobial Use measure to advance national efforts to reduce the emergence of antibiotic resistance by enabling hospitals and CMS to assess national trends of antibiotic use to facilitate improved stewardship by comparing antibiotic use that hospitals report to antibiotic use that is predicted based on nationally aggregated data. The measure was included on a publicly available document entitled "List of Measures Under Consideration for December 1, 2015," [134] in compliance with section 1890A(a)(2) of the Act. The measure received conditional support, pending CDC recommendation that the measure is ready for use in public reporting as referenced in the MAP 2016 Final

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[124] Spreadsheet of MAP 2016 Final Recommendations Available at: *http://www.qualityforum.org/map/.*

[125] Spreadsheet of MAP 2016 Final Recommendations Available at: *http://www.qualityforum.org/map/.*

[126] Centers for Disease Control and Prevention. Antibiotic Resistance Threats in the United States, 2013. Available from: *http://www.cdc.gov/drugresistance/threat-report-2013/.*

[127] Centers for Disease Control and Prevention. Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria. Available from: *http://www.hhs.gov/ash/carb/index.html.*

[128] National Strategy for Combating Antibiotic-Resistant Bacteria, 2014. Available from: *https://www.whitehouse.gov/sites/default/files/docs/carb_national_strategy.pdf.*

[129] National Action Plan for Combating Antibiotic-Resistant Bacteria, 2015. Available from: *https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibotic-resistant_bacteria.pdf.*

[130] Davey P, Brown E, Charani E, Fenelon L, Gould IM, Holmes A, et al. Interventions to improve antibiotic prescribing practices for hospital inpatients. Cochrane Database Syst Rev. 2013;4:CD003543.

[131] Feazel LM, Malhotra A, Perencevich EN, Kaboli P, Diekema DJ, Schweizer ML. Effect of antibiotic stewardship programmes on Clostridium difficile incidence: a systematic review and meta-analysis. J Antimicrob Chemother. 2014;69(7):1748–54. *http://jac.oxfordjournals.org/content/69/7/1748.full.pdf.*

[132] Kaki R, Elligsen M, Walker S, Simor A, Palmay L, Daneman N. Impact of antimicrobial stewardship in critical care: a systematic review. J Antimicrob Chemother. 2011;66(6):1223–30.

[133] Centers for Disease Control and Prevention. Core Elements of Hospital Antibiotic Stewardship Programs. Available from: *http://www.cdc.gov/getsmart/healthcare/implementation/core-elements.html.*

[134] 2015 Measures Under Consideration List Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367.*

Recommendations.[135] The MAP recognized the high importance of antimicrobial stewardship and conditionally supported the inclusion of this measure in the Hospital IQR Program while acknowledging that additional testing may be necessary to address feasibility issues for public reporting, quality implications of measuring the amount of antibiotics used versus appropriate use of antibiotics, and risk-adjustment. Further, MAP noted these issues should be addressed before the measure is reported on *Hospital Compare*.[136] The measure received endorsement from NQF on December 10, 2015.[137]

(2) Overview of Measure

The NHSN Antimicrobial Use measure assesses antibiotic use in hospitals based on medication administration data that hospitals collect electronically at the point of care. The measure compares antibiotic use that hospitals report, via electronic file submissions to the CDC's NHSN, to antibiotic use that is predicted based on nationally aggregated data. Data on administered antibiotics are required to be extracted from an electronic medication administration record (eMAR)[138] and/or bar coded medication administration (BCMA) system.[139] The antibiotic use data that are in scope for this measure include antibiotic agents administered to adult and pediatric patients in a specified set of ward and intensive care unit (ICU) locations. Locations include adult and pediatric medical, medical/surgical, and surgical wards and adult and pediatric medical, medical/surgical, and surgical ICUs as defined by the NHSN at: *http://www.cdc.gov/nhsn/PDFs/pscManual/15LocationsDescriptions_current.pdf*.

The measure is comprised of a discrete set of risk-adjusted summary ratios, known as Standardized Antimicrobial Administration Ratios (SAARS), which summarize observed-to-predicted antibacterial use for one of sixteen antibiotic agent-patient care location combinations. The specific antibiotic agent-location combinations were selected based on extensive consultation with infectious disease physicians and pharmacists at the forefront of ASPs. The specified categories of antibiotic agents include:

- Broad spectrum agents predominantly used for hospital-onset/multi-drug resistant bacteria;
- Broad spectrum agents predominantly used for community-acquired infection;
- Anti-MRSA agents; and
- Agents predominantly used for surgical site infection prophylaxis.

The SAARs are designed to serve as high value targets or high-level indicators for hospital ASPs to assess hospital antimicrobial use. A SAAR that is not significantly different from 1.0 indicates "expected" antibiotic use. A SAAR that is above 1.0 may indicate excessive antibiotic use or a SAAR that is below 1.0 may indicate antibiotic underuse. We note that the SAARs do not provide a definitive indication of antibiotic appropriateness of use. Outlier SAAR values should prompt hospitals to do further analysis to assess overuse, underuse, or inappropriate use of antibacterial medications. In addition, the SAARS may be used by hospital ASPs to identify opportunities to improve antibiotic use and gauge the impact of stewardship efforts.

(3) Data Sources

The data submission and reporting standard procedures for the NHSN Antimicrobial Use measure have been set forth by the CDC for NHSN participation, in general, and for submission of measure data. We refer readers to the CDC's NHSN Web site (*http://www.cdc.gov/nhsn*) for detailed data submission and reporting procedures. Although the NHSN Antimicrobial Use measure is not specified as an eCQM, manual data entry is not available. Data must be electronically extracted from an eMAR[140] and/or BCMA system.[141] The format for data submission must adhere to the data format prescribed by the CDC HL7 Clinical Data Architecture (CDA) Implementation Guide available at: *http://www.cdc.gov/nhsn/cdaportal/toolkits/guidetocdaversions.html*.

(4) Measure Calculation

Each SAAR is an observed to expected ratio and is calculated by dividing the numerator, or total number of observed antimicrobial days (days of therapy reported by a healthcare facility for a specified category of antimicrobial agents in a specified patient care location or group of locations), by the denominator, or expected (predicted on the basis of nationally aggregated AU data for a healthcare facility's use of a specified category of antimicrobial agents in a specified patient care location or group of locations) number of antimicrobial days, for each antibiotic agent category-patient care location combination. The total number of observed antimicrobial days for each patient care location is defined as the aggregated sum of days for which any amount of a specific antibiotic agent within an antibiotic agent category was administered as documented in the eMAR or BCMA system. The predicted number of antimicrobial days for each patient care location is determined by multiplying the observed days present by the corresponding antimicrobial use rate in the standard population obtained from the relevant regression model. Hospital patient care locations other than adult and pediatric medical, medical/surgical, and surgical wards and adult and pediatric medical, medical/surgical, and surgical ICUs are excluded from this measure. For more information regarding the specifications for the Antimicrobial Use measure, we refer readers to the NHSN Antimicrobial Use and Resistance Module (AUR): *http://www.cdc.gov/nhsn/PDFs/pscManual/11pscAURcurrent.pdf*.

We are inviting public comment on the possibility of future inclusion of the NHSN Antimicrobial Use Measure (NQF #2720).

c. Potential Measures for Behavioral Health in the Hospital IQR Program

Although the IPFQR Program incorporates measures of inpatient psychiatric treatment (80 FR 46694), the Hospital IQR Program does not include any measures directly related to behavioral health. Based on MedPAC analyses, over a third of Medicare inpatient psychiatric admissions are treated "in acute care hospital beds not within distinct-part psychiatric units."[142] Thus, there may be a gap in understanding the quality of care given to inpatient psychiatric patients not paid for under the IPFQR Program.

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[135] Spreadsheet of MAP 2016 Final Recommendations Available at: *http://www.qualityforum.org/map/*.

[136] Spreadsheet of MAP 2016 Final Recommendations Available at: *http://www.qualityforum.org/map/*.

[137] *http://www.qualityforum.org/QPS/2720*.

[138] eMAR is defined as technology that automatically documents the administration of medication into CEHRT using electronic tracking sensors (for example, radio frequency identification (RFID)) or electronically readable tagging such as bar coding (77 FR 54034).

[139] Barcode Medication Administration (BCMA) System is defined as a system that allows users to electronically document medications at the bedside or other points-of-care using an electronically readable format. More information. Available at: *http://www.ahrq.gov/downloads/pub/advances/vol3/wideman.pdf*.

[140] eMAR is defined as technology that automatically documents the administration of medication into CEHRT using electronic tracking sensors (for example, radio frequency identification (RFID)) or electronically readable tagging such as bar coding (77 FR 54034).

[141] Barcode Medication Administration (BCMA) System is defined as a system that allows users to electronically document medications at the bedside or other points-of-care using an electronically readable format. More information available at: *http://www.ahrq.gov/downloads/pub/advances/vol3/wideman.pdf*.

[142] Medicare Payment Advisory Commission (U.S.). (2010). MedPAC June 2010 Report to the

To address this gap, we are inviting public comments on potential behavioral health quality measures appropriate to include in the Hospital IQR Program in future years, including the possible use of one or more measures previously adopted in the IPFQR Program (80 FR 46417).

d. Potential Public Reporting of Quality Measures Data Stratified by Race, Ethnicity, Sex, and Disability and Future Hospital Quality Measures That Incorporate Health Equity

We are seeking comment on the possibility of including Hospital IQR Program measure data stratified by race, ethnicity, sex, and disability on *Hospital Compare*, if feasible and appropriate (that is, statistically appropriate, etc.) in the future. By stratification, we mean that we would report quality measures for each group of a given category (age, race, sex, and disability status). For example, if we were to report the Hospital-Wide All-Cause Unplanned Readmission Measure (HWR) (NQF #1789) stratified by sex, we would report a hospital's measure result for females and then again separately for males, in addition to reporting a hospital's unstratified rate, as is currently displayed.

In addition, we are also seeking comment on potential hospital quality measures, including composite measures, for inclusion in the Hospital IQR Program measure set and thus, future postings on *Hospital Compare*, that could help consumers and stakeholders not only assess the measurement of the quality of care furnished by hospitals in inpatient settings, but also monitor trends in health equity.

Any data pertaining to these areas that are recommended for collection through measure reporting for the Hospital IQR Program and public disclosure on *Hospital Compare*, would be addressed through a separate and future notice-and-comment rulemaking.

We are inviting public comment on the possibility of future inclusion of stratified quality measures data on *Hospital Compare* and on stratification categories, including any categories not specified in this preamble. We are also seeking comment on potential future hospital quality measures that incorporate health equity.

10. Form, Manner, and Timing of Quality Data Submission

a. Background

Sections 1886(b)(3)(B)(viii)(I) and (b)(3)(B)(viii)(II) of the Act state that the applicable percentage increase for FY 2015 and each subsequent year shall be reduced by one-quarter of such applicable percentage increase (determined without regard to sections 1886(b)(3)(B)(ix), (xi), or (xii) of the Act) for any subsection (d) hospital that does not submit data required to be submitted on measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary. Previously, the applicable percentage increase for FY 2007 and each subsequent fiscal year until FY 2015 was reduced by 2.0 percentage points for subsection (d) hospitals failing to submit data in accordance with the description above. In accordance with the statute, the FY 2016 payment determination began the second year that the Hospital IQR Program will reduce the applicable percentage increase by one-quarter of such applicable percentage increase.

In order to participate in the Hospital IQR Program, hospitals must meet specific procedural, data collection, submission, and validation requirements. For each Hospital IQR Program payment determination, we require that hospitals submit data on each specified measure in accordance with the measure's specifications for a particular period of time. The data submission requirements, Specifications Manual, and submission deadlines are posted on the QualityNet Web site at: *http://www.QualityNet.org/*. Hospitals must register and submit quality data through the secure portion of the QualityNet Web site. There are safeguards in place in accordance with the HIPAA Security Rule to protect patient information submitted through this Web site.

b. Procedural Requirements for the FY 2019 Payment Determination and Subsequent Years

The Hospital IQR Program's procedural requirements are codified in regulation at 42 CFR 412.140. We refer readers to these codified regulations for participation requirements, as further explained by the FY 2014 IPPS/LTCH PPS final rule (78 FR 50810 through 50811). In this proposed rule, we are not proposing any changes to these procedural requirements.

However, as discussed below in section VIII.A.11. of the preamble of this proposed rule, we are proposing to amend § 412.140(d)(2) in connection with our proposal to modify our validation processes beginning with the FY 2020 payment determination.

c. Data Submission Requirements for Chart-Abstracted Measures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51640 through 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53536 through 53537), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50811) for details on the Hospital IQR Program data submission requirements for chart-abstracted measures. In this proposed rule, we are not proposing any changes to the data submission requirements for chart-abstracted measures.

d. Proposed Alignment of the Hospital IQR Program With the Medicare and Medicaid EHR Incentive Programs for Eligible Hospitals and CAHs

(1) Background

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50256 through 50259) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49709) for our policies aligning eCQM data reporting and submission periods on a calendar year basis for both the Medicare EHR Incentive Program for eligible hospitals and CAHs and the Hospital IQR Program for the FY 2017 payment determination and subsequent years for the Hospital IQR Program.

In this section, we are proposing the following changes to the Hospital IQR Program to further align eCQM data reporting for the Hospital IQR Program with the Medicare and Medicaid EHR Incentive Programs: (1) Maintaining the eCQM data certification process we previously adopted for the FY 2018 payment determination, including requiring hospitals to report eCQM data using either the 2014 or 2015 Edition of the Office of the National Coordinator for Health Information Technology's (ONC's) certified electronic health record technology (CEHRT) for the CY 2017 reporting period/FY 2019 payment determination; and (2) requiring the use of the 2015 Edition of CEHRT beginning with the CY 2018 reporting period/FY 2020 payment determination and subsequent years.

In addition, we are proposing to require eCQM data submission by the end of 2 months following the close of the reporting period calendar year for the CY 2017 reporting period/FY 2019 payment determination and subsequent years to further align eCQM data reporting for the Hospital IQR Program with the Medicare EHR Incentive Program. These proposals are discussed in more detail below.

Congress: . Washington, DC: MedPAC, available at: *http://www.medpac.gov/documents/reports/Jun10_Ch06.pdf?sfvrsn=0.*

(2) Proposed Continuation of eCQM Certification Processes for the FY 2019 Payment Determination and Proposals for Subsequent Years

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49708), we finalized policies regarding eCQM certification for the FY 2018 payment determination. Specifically, we finalized that: (1) Hospitals can report using either the 2014 or 2015 Edition of CEHRT for the CY 2016 reporting period/FY 2018 payment determination since certification to the 2015 Edition is expected to be available in 2016; and (2) hospitals must submit eCQM data via Quality Reporting Document Architecture (QRDA) Category I file (80 FR 49707–49708). In addition, hospitals may use third parties to submit QRDA I files on their behalf (80 FR 49706) and can either use abstraction or pull the data from non-certified sources in order to then input these data into CEHRT for capture and reporting QRDA I (80 FR 49706).

We are proposing to continue these eCQM certification policies. Specifically, for the CY 2017 reporting period/FY 2019 payment determination (not subsequent years), we are proposing to require that hospitals report using either the 2014 or 2015 Edition of CEHRT as previously required. We note that we are proposing to change these policies, however, for the CY 2018 reporting period/FY 2020 payment determination as discussed in the following section.

In addition, for the CY 2017 reporting period/FY 2019 payment determination and subsequent years, we are proposing that hospitals: (1) Must submit eCQM data via QRDA I files as previously required; (2) may continue to use a third party to submit QRDA I files on their behalf; and (3) continue to either use abstraction or pull the data from non-certified sources in order to then input these data into CEHRT for capture and reporting QRDA I. This would align the Hospital IQR Program with the Medicare EHR Incentive Program. We refer readers to section VIII.E.2.c. of the preamble of this proposed rule for discussion of the proposed certification requirements for the Medicare EHR Incentive Program.

We are inviting comment on these proposals. In addition, we refer readers to section VIII.A.11.b.(4) of the preamble of this proposed rule where we encourage hospitals to take advantage of eCQM pre-submission testing tools to help reduce submission errors related to improperly formatted QRDA I files.

(3) Proposed Required Use of EHR Technology Certified to the 2015 Edition for the FY 2020 Payment Determination and Subsequent Years

As stated in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705), some commenters requested that hospitals be given the opportunity to use the most recent version of the CEHRT (2015 Edition) for the CY 2016 reporting period/FY 2018 payment determination if they are able. We believe this requirement will mitigate the existing vendor issue of system comparability between hospitals and vendors and facilitate consistency regarding the version of CEHRT to which vendors are certified by establishing uniformity in the version of the product used. Therefore, we are proposing to require the use of EHR technology certified to the 2015 Edition beginning with the CY 2018 reporting period for the FY 2020 payment determination and subsequent years. This would align the Hospital IQR Program with the Medicare EHR Incentive Program. We refer readers to section VIII.E.2.c. of the preamble of this proposed rule for discussion of the proposed certification requirements for the Medicare EHR Incentive Program.

We are inviting public comment on our proposal to require the use of EHR technology certified to the 2015 Edition for the CY 2018 reporting period/FY 2020 payment determination and subsequent years as stated above.

(4) Proposed Electronic Submission Deadlines for the FY 2019 Payment Determination and Subsequent Years

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50256 through 50259) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49708) for our previously adopted policies to align eCQM data reporting and submission periods for both the Medicare EHR Incentive Program for eligible hospitals and CAHs and the Hospital IQR Program for the FY 2018 payment determination.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50249 through 50252), we finalized our policy that hospitals may voluntarily report 16 electronic measures by submitting one quarter of eCQM data from CY Q1 (January 1-March 31, 2015), CY Q2 (April 1-June 30, 2015), or CY Q3 (July 1-September 30) by November 30, 2015. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49693 through 49698), for the FY 2018 payment determination, we finalized a policy that hospitals must submit one quarter of data (either Q3 or Q4 of CY 2016) for at least 4 eCQMs by the submission deadline of February 28, 2017.

In this year's proposed rule, in order to align the Hospital IQR Program eCQM data submission deadline with that of the Medicare EHR Incentive Program, which requires eCQM data submission by the end of two months following the close of the reporting period calendar year (80 FR 62896 through 62897), we are proposing to establish an eCQM submission deadline for the Hospital IQR Program which requires eCQM data submission by the end of two months following the close of the calendar year for the CY 2017 reporting period/FY 2019 payment determination and subsequent years. For example, for the CY 2017 reporting period/FY 2019 payment determination, hospitals would be required to submit eCQM data for the Hospital IQR Program by February 28, 2018, which is the end of 2 months following the close of the calendar year (December 31, 2017). This would align the Hospital IQR Program with the Medicare EHR Incentive Program deadlines. We note that deadlines for the Medicaid (not Medicare) EHR Incentive Program differ by State, and therefore our proposal to align data submission deadlines for eCQMs applies only to the Hospital IQR Program and the Medicare EHR Incentive Program and not to the Medicaid EHR Incentive Program. For more information about the Medicaid EHR Incentive Program for eligible hospitals and CAHs, we refer readers to: *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Eligible_Hospital_Information.html.*

We are inviting public comment on our proposal to align the Hospital IQR Program eCQM submission deadline with that of the Medicare EHR Incentive Program for the CY 2017 reporting period/FY 2019 payment determination and subsequent years as discussed above.

(5) Summary of Alignment

We are proposing to align the Hospital IQR Program with the Medicare and Medicaid EHR Incentive Programs as summarized below:

Alignment of Hospital IQR Program with both the Medicare and Medicaid EHR Incentive Programs
• Proposed removal of 13 eCQMs • Proposed requirement for submission of all available eCQMs

Alignment of Hospital IQR Program with both the Medicare and Medicaid EHR Incentive Programs
• Proposed requirement for annual submission of four quarters of eCQM data • Proposed continued use of 2014 or 2015 CEHRT for CY 2017 reporting period/FY2019 payment determination • Proposed use of 2015 CEHRT for CY 2018 reporting period/FY2020 payment determination
Alignment of Hospital IQR Program with only the Medicare EHR Incentive Program
• Proposed submission of eCQM data 2 months following the close of the calendar year

e. Sampling and Case Thresholds for the FY 2019 Payment Determination and Subsequent Years

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50221), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819) for details on our sampling and case thresholds for the FY 2016 payment determination and subsequent years. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 24588), we revised our sampling and case thresholds policy so that, for the FY 2018 payment determination and subsequent years, hospitals will be required to submit population and sample size data only for those measures that a hospital submits as chart-abstracted measures under the Hospital IQR Program.

We are not proposing any changes to our sampling and case thresholds policy in this proposed rule.

f. HCAHPS Requirements for the FY 2019 Payment Determination and Subsequent Years

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641 through 51643), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537 through 53538), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819 through 50820) for details on previously-adopted HCAHPS requirements. We also refer hospitals and HCAHPS survey vendors to the official HCAHPS Web site at *http://www.hcahpsonline.org* for new information and program updates regarding the HCAHPS Survey, its administration, oversight, and data adjustments. In this proposed rule, we are not proposing any changes to the HCAHPS requirements.

g. Data Submission Requirements for Structural Measures for the FY 2019 Payment Determination and Subsequent Years

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51643 through 51644) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53538 through 53539) for details on the data submission requirements for structural measures. In this proposed rule, we are not proposing any changes to data submission requirements for structural measures.

h. Data Submission and Reporting Requirements for HAI Measures Reported via NHSN

For details on the data submission and reporting requirements for HAI measures reported via the CDC's NHSN Web site, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51629 through 51633; 51644 through 51645), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50821 through 50822), and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50259 through 50262). The data submission deadlines are posted on the QualityNet Web site at: *http://www.QualityNet.org/*. In this proposed rule, we are not proposing any changes to data submission and reporting requirements for HAI measures reported via the NHSN.

11. Proposed Modifications to the Existing Processes for Validation of Hospital IQR Program Data

a. Background

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539 through 53553), we finalized the processes and procedures for validation of chart-abstracted measures in the Hospital IQR Program for the FY 2015 payment determination and subsequent years; the FY 2013 IPPS/LTCH PPS final rule also contains a comprehensive summary of all procedures finalized in previous years that are still in effect. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50822 through 50835), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50262 through 50273), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49710 through 49712) for detailed information on the modifications to these processes finalized for the FY 2016, FY 2017, and FY 2018 payment determinations and subsequent years.

In this proposed rule, we are proposing to update the validation process in order to incorporate a process for validating eCQM data.

b. Proposed Modifications to the Existing Processes for Validation of Hospital IQR Program Data

(1) Background

In this proposed rule, we are proposing to update the existing process for validation of Hospital IQR Program data, which has previously included up to 600 hospitals for chart-abstracted validation, to also include eCQM validation of up to 200 hospitals, for a total of up to 800 hospitals for validation for the FY 2020 payment determination and subsequent years. Specifically, 200 hospitals would be randomly selected for eCQM validation but among those hospitals some may be granted Extraordinary Circumstances Exception (ECE) waivers or meet other exclusion criteria (discussed in additional detail below) potentially resulting in a number totaling less than 200 hospitals that actually participate in eCQM validation. Furthermore, we are proposing that hospitals would be required to submit timely and complete medical record information from the Electronic Health Records (EHR) for at least 75 percent of sampled records, but would not be scored on the basis of measure accuracy for FY 2020 payment determinations.

As we stated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53555), determining the equivalence of eCQM data and chart-abstracted measures data requires extensive testing given that the data for the Hospital IQR Program support public reporting for both the Hospital IQR and the Hospital VBP Programs; in addition, for the Hospital VBP Program, the data are used to calculate hospitals' performance on a subset of measures which tie payment directly to measure performance. As described in the Hospital IQR Program discussion in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50258), we have received anecdotal comments about performance level differences between chart-abstracted and eCQM data. We stated that we did not have sufficient data to be able to confirm or refute the accuracy of those comments (79 FR 50258). In order to substantiate or refute the existence of performance-level differences between eCQM data and chart-abstracted measure data, we believe that we must collect more eCQM data and develop a process for validating the accuracy of that data.

As a result, we conducted a validation pilot test for eCQMs (discussed below). Our findings from this pilot test have informed what we believe the initial future direction of eCQM validation in the Hospital IQR Program should be. In this proposed rule, we are proposing to adopt a validation process for eCQM data submissions beginning in spring of CY 2018, as further explained below.

(2) Validation Pilot Test

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50269 through 50273), we finalized a proposal to conduct a validation pilot test for eCQMs in FY 2015. The results of the pilot test yielded measure record matching rates (that is, the rates of medical record abstracted values as compared to the values reported in the QRDA I file) of less than 50 percent for all of the measures reported. For all measures, the inconsistencies between abstracted values and values reported in the QRDA I files appear to be mainly due to missing data rather than actual differences in reported versus abstracted values. The highest rate of accuracy was 48 percent on both the STK–04 and VTE–1 eCQM measures. In addition, all of the participating hospitals demonstrated significant difficulty in reporting the ED–1 and ED–2 eCQM measures due to the ED Admit Date/Time data element, which contributed to the ED measure mismatch rates. Specifically, hospitals systematically reported a later date and time for the decision to admit a patient to the hospital in the QRDA I file than that identified by the Clinical Data Abstraction Center (CDAC) in the review of the medical record.

Follow-up interviews conducted by CDAC revealed that low accuracy rates and reporting difficulties were a result of a lack of targeted outreach and education efforts at the time of the pilot to adequately prepare participating hospitals for the specific reporting mechanisms. In order to improve data accuracy and diminish reporting difficulties, the CMS Outreach and Education contractor (EOC) as well as the Validation Support Contractor (VSC) plan to continue to conduct provider education follow-up and refine the validation process. We will work in conjunction with the EOC and VSC to enlarge the cohort of eligible hospitals that are able to successfully submit QRDA I files, as well as encourage hospitals that were not able to successfully submit QRDA I files to participate in follow-up interviews. These follow-up interviews will inform the eCQM validation process moving forward, and allow us to derive "best reporting practices" to consider once we begin scoring the measures.

(3) Proposal To Validate eCQMs Beginning Spring CY 2018/FY 2020 Payment Determination

In response to the findings of the pilot test and in light of our proposal to increase the number of eCQMs on which hospitals are required to submit data for the Hospital IQR Program in section VIII.A.8.a. of the preamble of this proposed rule, we believe that it is increasingly important to validate eCQM data to ensure the accuracy of future information submitted by hospitals and reported to the public. Therefore, we are proposing to adopt a validation process for eCQM data submissions beginning in spring of CY 2018, as further explained below.

(a) Number and Selection of Hospitals

We are proposing to validate eCQM data submitted by up to 200 hospitals selected via random sample. Furthermore, we are proposing that the following hospitals be excluded from this random sample of 200 hospitals selected for eCQM validation:

- Any hospital selected for chart-abstracted measure validation; and
- Any hospital that has been granted a Hospital IQR Program "Extraordinary Circumstances Exemption" for the applicable eCQM reporting period.

We acknowledge that the burden associated with both the chart-abstracted and eCQM validation processes would be significant. We do not intend to impose an undue burden on any hospital by requiring that it be subject to more than one of these processes in a program year. Thus, if a hospital is selected for chart-abstracted targeted or random validation, we are proposing that hospital would be excluded from the eCQM validation sample.

In addition, although our targeted criteria permit that a hospital may be selected for chart-abstracted validation even if it has been granted an Extraordinary Circumstances Exemption with respect to one or more chart-abstracted measures for the applicable data collection period (77 FR 53552 through 53553), if a hospital is granted an Extraordinary Circumstances Exemption with respect to eCQM reporting for the applicable eCQM reporting period, we are proposing that the hospital would be excluded from the eCQM validation sample due to its inability to supply data for validation. We note that due to these proposed exclusions, the total number of hospitals validated for eCQMs might be less than 200.

Adding the proposed eCQM validation would result in a total of 800 hospitals in the validation process, as described in the below tables.

Current Validation Process Number of Hospitals		**Proposed Validation Process Number of Hospitals**	
Chart-Abstracted Random	400	Chart-Abstracted Random	400
Chart-Abstracted Targeted	200	Chart-Abstracted Targeted	200
		eCQM: random	200
Total	600		800

We believe that as we expand the required reporting of eCQMs in the Hospital IQR Program, we need to validate eCQM data to ensure the accuracy of information submitted by hospitals and reported to the public, as well as for future consideration of eCQMs for potential use in the Hospital VBP Program. In addition, during the first round of eCQM validation, we could better assess strategies to offset the resources required to conduct a scored method of eCQM validation for future rulemaking cycles.

We are inviting public comment on our proposals for the FY 2020 payment determination and subsequent years to: (1) Validate eCQM data submitted by up to 200 hospitals selected via random sample; and (2) to exclude any hospital selected for chart-abstracted measure validation as well as any hospital that has been granted a Hospital IQR Program "Extraordinary Circumstances Exemption" for the applicable eCQM reporting period as discussed above.

(b) Number of Cases

We are proposing to randomly select 32 cases (individual patient-level reports) from the QRDA I file submitted per hospital selected for eCQM validation. Each randomly selected case (individual patient-level report) contains eCQM data elements[143] for one patient for one or more eCQMs available in the program's eCQM measure set. The CDAC would then request that each of the selected hospitals submit patient medical record data for each of their 32 randomly selected cases (transmitted by the hospital to the Clinical Data Warehouse) within 30 days of the medical records request date. We refer readers to our discussion in section VIII.A.11.b.(3)(c) of the preamble of this proposed rule, below, for more information on our proposed submission requirements.

Based on the statistical properties of estimates as discussed below, we believe that a sample size of 32 cases is necessary to assess hospital performance on eCQMs. More specifically, at the individual hospital level, if we assume the average agreement rate between the QRDA I file data and data abstracted from the patient medical record is around 90 percent, and we want the hospital's confidence interval to vary by no more than plus or minus 10 percentage points (80 to 100 percent), then we need to select at least 32 cases per year. Also, 32 cases aligns with the number of cases currently selected for chart-abstracted validation of clinical process of care measures. We currently select eight cases per quarter per hospital, which equates to 32 cases annually (79 FR 50264).

We are inviting public comment on our proposal to randomly select 32 cases from the QRDA I file submitted per hospital selected for eCQM validation for the FY 2020 payment determination and subsequent years as discussed above.

(c) Submission Requirements

We are proposing to require hospitals selected for eCQM validation to submit timely and complete medical record information to CMS on eCQMs selected for the validation sample. These are defined below.

Consistent with the Hospital IQR Program chart-abstracted and NHSN validation submission deadline, which is 30 calendar days following the medical records request date listed on the CDAC request form (76 FR 51645), we are proposing to require eCQM validation submission by 30 calendar days following the medical records request date listed on the CDAC request form for the FY 2020 payment determination and subsequent years. Also, we are proposing to require sufficient patient level information (defined below) necessary to match the requested medical record to the original Hospital IQR Program submitted eCQM measure data record for the FY 2020 payment determination and subsequent years. Sufficient patient level information is defined as the entire medical record that sufficiently documents the eCQM measure data elements, which would include but would not be limited to, patient arrival date and time, inpatient admission date, and discharge date from inpatient episode of care. Lastly, we are proposing that, if selected as part of the random sample for eCQM validation, a hospital would be required to submit records in PDF file format through QualityNet using the Secure File Transfer (SFT) for the FY 2020 payment determination and subsequent years. The data submission deadlines and additional details about the eCQM validation procedures would be posted on the QualityNet Web site at: *http://www.QualityNet.org/.*

We are inviting public comment on our proposals regarding eCQM validation submission requirements for the FY 2020 payment determination and subsequent years as discussed above.

(d) Scoring: Summary of Previously Adopted Chart-Abstracted Measure Validation Scoring

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50226 through 50227), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539 through 53553), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50832 through 50833), and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50268 through 50269), for a detailed description of our previously adopted scoring methodology for chart-abstracted measure data.

We note that we are not proposing any changes to our chart-abstracted measures validation. We are providing this information as background for our discussion of eCQM validation scoring. Under the current validation process for the Hospital IQR Program there are 600 hospitals (400 randomly sampled and 200 targeted) selected for validation on a yearly basis. As stated above, those selected for chart-abstracted measure validation would not be eligible for selection to participate in eCQM validation. For chart-abstracted measure validation, the CDAC contractor requests hospitals to submit 8 randomly selected medical charts on a quarterly basis from which data were abstracted and submitted by the hospital to the Clinical Data Warehouse (for a total of 32 charts per year). Under the validation methodology, once the CDAC contractor receives the charts, it reabstracts the same data submitted by the hospitals and calculates the percentage of matching Hospital IQR Program measure numerators and denominators for each measure within each chart submitted by the hospital. Each selected case has multiple measures included in the validation score. Consistent with previous years, each quarter and clinical topic is treated as a stratum for variance estimation purposes (70 FR 47423).

As in previous years, for the FY 2020 payment determination, the overall validation score from the chart-abstracted measure validation will be used to determine a hospital's overall annual payment update. Specifically, if a hospital fails chart-abstracted validation, it would not receive the full annual payment update. If a hospital passes chart-abstracted validation, and also meets the other Hospital IQR Program requirements, it would be eligible to receive the full annual payment update. Consistent with previous years, a hospital must attain at least a 75 percent validation score (the percentage of matching Hospital IQR Program measure numerators and denominators for each measure within each chart submitted by the hospital) based upon chart-abstracted data validation to pass the validation requirement and to be eligible for a full annual payment update, if all other Hospital IQR Program requirements are met.

(e) Scoring: Proposals for eCQM Validation Scoring

For the FY 2020 payment determination, for hospitals selected for eCQM validation, we are proposing to require submission of at least 75 percent of sampled eCQM measure medical records in a timely and complete manner. However, unlike chart-abstracted validation, which requires a hospital to attain at least a 75 percent validation score, we are proposing that the accuracy of eCQM data (the extent to which data abstracted for validation matches the data submitted in the QRDA I file) submitted for validation would not affect a hospital's validation score for the FY 2020 payment determination only. This is further explained below.

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[143] A data element is a representation of a clinical concept that represents a patient state or attribute. This may be a diagnosis, lab value, sex, etc., which is encoded using standardized terminologies. The e-specifications for an eCQM include the data elements, logic, and definitions for that measure, available from: *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Electronic_Reporting_Spec.html.*

Public comments on the FY 2015 IPPS/LTCH PPS final rule suggested further refinements to the process for eCQM validation. Specifically, several commenters urged CMS to implement the recommendations of a March 2014 Government Accountability Office (GAO) report to develop a comprehensive data collection strategy, which includes testing for and mitigation of reliability issues arising from variance in certified EHR systems tested to different CQM specifications (79 FR 50272). Commenters in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49711) expressed concern over the barriers hospitals encounter associated with reporting eCQMs and encouraged CMS to ensure that a diverse group of hospitals and certified EHRs are represented to inform an assessment of the work required to make eCQM validation feasible, reliable, and valid. In response to these concerns, in light of operational capacity limitations, and due to the time necessary to analyze eCQM validation results, we are proposing that eCQM data would be validated, but initially (meaning for the FY 2020 payment determination only), the measure accuracy would not affect hospitals' validation scores.

In other words, although hospitals would be required to submit eCQM data in a timely and complete manner, we are proposing that hospitals would not be required to attain at least a 75 percent validation score (the percentage of matching Hospital IQR Program measure numerators and denominators for each measure within each chart submitted by the hospital) based upon QRDA I validation to pass the validation requirement and to be eligible for a full annual payment update. Hospitals that submit at least 75 percent of sampled eCQM measure medical records (even if those records do not produce a validation score of at least 75 percent) in a timely manner (that is, within 30 days of the date listed on the CDAC medical records request) would not be subject to payment reduction. However, hospitals that fail to submit timely and complete information for at least 75 percent of requested records would not meet the eCQM validation requirement and would be subject to payment reduction. For example, if a hospital submits timely and complete information for at least 75 percent of requested records, but comparison of the QRDA I file and the abstracted data results in a validation score of 28 percent, the hospital still would pass validation and be eligible for a full annual payment update.

Hospitals that pass either chart-abstracted or eCQM validation requirements would receive their full annual payment update, assuming all other Hospital IQR Program requirements are met. Hospitals that fail to attain at least a 75-percent validation score for chart-abstracted validation or fail to submit timely and complete data for 75 percent of requested records for eCQM validation, would not receive their full annual payment update.

In addition, we are proposing to update our regulations at 42 CFR 412.140(d)(2) to reflect the above proposals and to specify that the 75 percent score would only apply to chart-abstracted validation.

We are inviting public comment on our eCQM validation scoring proposals for the FY 2020 payment determination as discussed above.

(4) Reimbursement for eCQM Validation

To align with the chart-abstracted validation process, which reimburses hospitals at a rate of $3.00 per chart (78 FR 50956) for submitting charts electronically via Secure File Transfer (SFT), we are proposing to similarly reimburse hospitals at a rate of $3.00 per chart for submitting charts electronically via Secure File Transfer (SFT) for eCQM validation for the FY 2020 payment determination and subsequent years. We also refer readers to section X.B.6. of the preamble of this proposed rule for more information regarding the collection of information for eCQM validation.

We are inviting public comment on our proposal to reimburse hospitals at a rate of $3.00 per chart for eCQM validation for the FY 2020 payment determination and subsequent years as discussed above.

(5) eCQM Pre-Submission Testing

We are encouraging hospitals to test their eCQM submissions prior to annual reporting using an available CMS pre-submission validation tool for electronic reporting—the Pre-submission Validation Application (PSVA), which can be downloaded from the Secure File Transfer (SFT) section of the QualityNet Secure Portal at *https://cportal.qualitynet.org/QNet/pgm_select.jsp*. The PSVA is a downloadable tool that operates on a user's system to allow submitters to catch and correct errors prior to data submission to CMS. It provides validation feedback within the submitter's system and allows valid files to be separated and submitted while identifying invalid files for error correction.[144] While the PSVA does not guarantee the accuracy of data in a hospital's QRDA I file, it helps to reduce submission errors related to improperly formatted QRDA I files. Pre-submission testing would assist in proactively identifying inconsistencies in data mapping, a process used in data warehousing by which different data models are linked to each other using a defined set of methods to characterize the data in a specific definition.[145]

12. Data Accuracy and Completeness Acknowledgement (DACA) Requirements for the FY 2019 Payment Determination and Subsequent Years

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554) for previously-adopted details on DACA requirements. We are not proposing any changes to the DACA requirements in this proposed rule.

13. Public Display Requirements for the FY 2019 Payment Determination and Subsequent Years

We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47364), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50230), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277), and the FY 2016 final rule (80 FR 49712 through 49713) for details on public display requirements. The Hospital IQR Program quality measures are typically reported on the *Hospital Compare* Web site at: *http://www.medicare.gov/hospitalcompare*, but on occasion are reported on other CMS Web sites such as *https://data.medicare.gov*. We are not proposing any changes to our public display requirements in this proposed rule.

14. Reconsideration and Appeal Procedures for the FY 2019 Payment Determination and Subsequent Years

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650 through 51651), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), and 42 CFR 412.140(e) for details on reconsideration and appeal procedures for the FY 2017 payment determination and subsequent years. We are not proposing any changes to the reconsideration and appeals procedures in this proposed rule.

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[144] PSVA Demonstration and eCQM Question and Answer Session. Available at: *http://www.qualityreportingcenter.com/wp-content/uploads/2016/03/3–10–16-eCQM_PSVA-Demonstration_FINAL508.pdf*.

[145] Data Mapping Definition Available at: *https://www.techopedia.com/definition/6750/data-mapping*.

15. Proposed Changes to the Hospital IQR Program Extraordinary Circumstances Extensions or Exemptions (ECE) Policy

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651 through 51652), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836 through 50837), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713), and 42 CFR 412.140(c)(2) for details on the Hospital IQR Program ECE policy. We also refer readers to the QualityNet Web site at *http://www.QualityNet.org/* for our current requirements for submission of a request for an extension or exemption.

In this proposed rule, we are proposing to update our ECE policy by: (1) Extending the general ECE request deadline for non-eCQM circumstances from 30 to 90 calendar days following an extraordinary circumstance; and (2) establishing a separate submission deadline for ECE requests related to eCQM reporting circumstances to be April 1 following the end of the reporting calendar year. We are proposing that these policies would apply beginning in FY 2017 as related to extraordinary circumstance events that occur on or after October 1, 2016.

a. Proposal To Extend the General ECE Request Deadline for Non-eCQM Circumstances

In the past, we have allowed hospitals to submit an ECE request form for non-eCQM measures within 30 calendar days following an event that causes hardship and prevents them from providing data for non-eCQM measures (76 FR 51652). In certain circumstances, however, it may be difficult for hospitals to timely evaluate the impact of a certain extraordinary event within 30 calendar days. We believe that extending the deadline to 90 calendar days would allow hospitals more time to determine whether it is necessary and appropriate to submit an ECE request and to provide a more comprehensive account of the "event" in their ECE request form to CMS. For example, if a hospital has suffered damage due to a hurricane on January 1, it would have until March 31 to submit an ECE form via the QualityNet Secure Portal, mail, email, or secure fax as instructed on the ECE form. This proposed timeframe (90 calendar days) also aligns with the ECE request deadlines for the Hospital VBP Program (78 FR 50706), the HAC Reduction Program (80 FR 49580) and the Hospital Readmissions Reduction Program (80 FR 49542 through 49543), all of which at least partially rely on the same data collection.

b. Proposal To Establish a Separate Submission Deadline for ECE Requests Related to eCQMs

In addition, we are proposing to establish a separate submission deadline for ECE requests with respect to eCQM reporting, such that hospitals must submit a request by April 1 following the end of the reporting calendar year. We are proposing that this deadline for ECE requests with respect to eCQM reporting would first apply with an April 1, 2017 deadline and apply for subsequent eCQM reporting years. For example, for data collected for the CY 2016 reporting period (through December 31, 2016), hospitals would have until April 1, 2017 to submit an ECE request. This timeframe also aligns with the Medicare and Medicaid EHR Incentive Programs' typical annual hardship request deadline (77 FR 54104 through 54109), which we believe would help reduce burden for hospitals.

We are inviting public comment on our proposals related to the Hospital IQR Program's ECE policy beginning FY 2017 as described above.

B. PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

1. Background

Section 3005 of the Affordable Care Act added new sections 1866(a)(1)(W) and (k) to the Act. Section 1866(k) of the Act establishes a quality reporting program for hospitals described in section 1886(d)(1)(B)(v) of the Act (referred to as "PPS-Exempt Cancer Hospitals" or "PCHs") that specifically applies to PCHs that meet the requirements under 42 CFR 412.23(f). Section 1866(k)(1) of the Act states that, for FY 2014 and each subsequent fiscal year, a PCH must submit data to the Secretary in accordance with section 1866(k)(2) of the Act with respect to such fiscal year. For additional background information, including previously finalized measures and other policies for the PCHQR Program, we refer readers to the following final rules: FY 2013 IPPS/LTCH PPS final rule (77 FR 53556 through 53561); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50838 through 50846); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277 through 50288); and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713 through 49723).

2. Proposed Criteria for Removal and Retention of PCHQR Program Measures

We have received public comments on past proposed rules asking that we clarify our policy for measure retention and removal. We generally retain measures from the previous year's PCHQR Program measure set for subsequent years' measure sets, except when we specifically propose to remove or replace a measure. With respect to measure removal, we believe it is important to be transparent in identifying criteria that we would use to evaluate a measure for potential removal from the PCHQR Program. We also believe that we should align these criteria between our programs whenever possible.

Therefore, we are proposing the following measure removal criteria for the PCHQR Program, which are based on criteria established in the Hospital IQR Program (80 FR 49641 through 49642):

- Measure performance among PCHs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made ("topped-out" measures);
- A measure does not align with current clinical guidelines or practice;
- The availability of a more broadly applicable measure (across settings or populations) or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;
- Performance or improvement on a measure does not result in better patient outcomes;
- The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic;
- Collection or public reporting of a measure leads to negative unintended consequences other than patient harm; and
- It is not feasible to implement the measure specifications.

For the purposes of considering measures for removal from the program, we would consider "topped-out" to be that there is statistically indistinguishable performance at the 75th and 90th percentiles and that the truncated coefficient of variation is less than or equal to 0.10.

However, we recognize that there are times when measures may meet some of the outlined criteria for removal from the program, but continue to bring value to the program. Therefore, we are proposing the following criteria for consideration in determining whether to retain a measure in the PCHQR Program, which also are based on criteria established in the Hospital IQR Program (80 FR 49641 through 49642):

- Measure aligns with other CMS and HHS policy goals;
- Measure aligns with other CMS programs, including other quality reporting programs; and
- Measure supports efforts to move PCHs towards reporting electronic measures.

We welcome public comments on these proposed measure removal and retention criteria.

3. Retention and Proposed Update to Previously Finalized Quality Measures for PCHs Beginning With the FY 2019 Program Year

a. Background

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53556 through 53561), we finalized five quality measures for the FY 2014 program year and subsequent years. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50837 through 50847), we finalized one new quality measure for the FY 2015 program year and subsequent years and 12 new quality measures for the FY 2016 program year and subsequent years. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50278 through 50280), we finalized one new quality measure for the FY 2017 program year and subsequent years. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713 through 49719), we finalized three new CDC NHSN measures for the FY 2018 program year and subsequent years, and finalized the removal of six previously finalized measures for fourth quarter (Q4) 2015 discharges and subsequent years. We refer readers to the final rules referenced in section VIII.B.1. of the preamble of this proposed rule for more information regarding these previously finalized measures.

We are not proposing for FY 2019 to remove any of the measures previously finalized for the FY 2018 program year from the PCHQR measure set. However, we are proposing to update the Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382) measure, described below.

b. Proposed Update of Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382) Measure for FY 2019 Program Year and Subsequent Years

Beginning with the FY 2019 program year, we are proposing to update the specifications of the Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382) measure. This measure was originally finalized in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50841 through 50842). In November 2014, subsequent to our adoption of the measure in the PCHQR Program, updated specifications were endorsed by the NQF.

The updated measure specifications expand the patient cohort to include patients receiving 3D conformal radiation therapy for breast or rectal cancer in addition to patients receiving 3D conformal radiation therapy for lung or pancreatic cancers (the original cohort).[146] For additional information about the original measure cohort, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50842), in which we introduced the measure to the PCHQR Program. In 2012, breast cancer was the most common cancer among women, and the second most common cause of cancer related deaths for women.[147] For 2016, the National Institutes of Health estimates that there will be approximately 135,000 new cases of colorectal cancer in the United States, with approximately 39,000 of these cases being rectal cancer.[148]

As these cancer types are so prevalent, we believe that the expansion of the measure cohort to include breast and rectal cancer patients is important to ensuring the delivery of high quality care in the PCH setting. In compliance with section 1890A(a)(2) of the Act, this measure update was included in a publicly available document, "List of Measures under Consideration for December 1, 2015." [149] The MAP, a multi-stakeholder group convened by the NQF, reviews the measures under consideration for the PCHQR Program, among other Federal programs, and provides input on those measures to the Secretary. The MAP's 2016 recommendations for quality measures under consideration are captured in the following document: "Process and Approach for MAP Pre-Rulemaking Deliberations 2015–2016" (*http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81599*). The MAP expressed conditional support for the update of Oncology: Radiation Dose Limits to Normal Tissues. The MAP's conditional support was solely pending annual NQF review, and was not based on significant concerns. We considered the input and recommendations provided by the MAP, and the importance of aligning with NQF-endorsed specifications of measures whenever possible, in proposing this update for the PCHQR Program.

We welcome public comments on this proposal for the Oncology: Radiation Dose Limits to Normal Tissues measure cohort expansion for the FY 2019 program year and subsequent years.

4. Proposed New Quality Measure Beginning With the FY 2019 Program Year

a. Considerations in the Selection of Quality Measures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53556), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50837 through 50838), and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50278), we indicated that we have taken a number of principles into consideration when developing and selecting measures for the PCHQR Program, and that many of these principles are modeled on those we use for measure development and selection under the Hospital IQR Program. In this proposed rule, we are not proposing any changes to the principles we consider when developing and selecting measures for the PCHQR Program.

Section 1866(k)(3)(A) of the Act requires that any measure specified by the Secretary must have been endorsed by the entity with a contract under section 1890(a) of the Act (the NQF is the entity that currently holds this contract). Section 1866(k)(3)(B) of the Act provides an exception under which, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization.

Using the principles for measure selection in the PCHQR Program, we are proposing one new measure, described below.

b. Proposed Adoption of the Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy Measure

We are proposing to adopt the Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy measure for the FY 2019 program year and subsequent years. Cancer care is a priority area for outcome measurement because cancer is an increasingly prevalent condition associated with considerable morbidity and mortality. In 2015, there were more than 1.6 million new cases of cancer in the United States.[150] Each year, about 22 percent of cancer patients receive chemotherapy,[151] with Medicare payments for cancer treatment totaling $34.4 billion in 2011 or almost 10 percent of Medicare fee-for-service (FFS) spending.[152] With an increasing number of cancer patients receiving chemotherapy in a hospital outpatient department,[153] a growing body of peer-reviewed literature identifies unmet needs in the care provided to these patients. This gap in care may be due to reasons including: (1) Delayed onset of side effects that patients must manage at home; (2) patients assuming that little can be done and not seeking assistance; and (3) limited access to and communication with providers who can tailor care to the individual.[154] As a result, cancer patients that receive chemotherapy in a hospital outpatient department require more frequent acute care in the hospital setting and experience more adverse events than cancer patients that are not receiving chemotherapy.[155] [156] [157]

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[146] Available at: *http://www.qualityforum.org/QPS/0382*.

[147] CDC Breast Cancer Statistics. Available at: *http://www.cdc.gov/cancer/breast/statistics/*.

[148] NIH Colorectal Cancer Incidence and Mortality. Available at: *http://www.cancer.gov/types/colorectal/hp/rectal-treatment-pdq*.

[149] CMS List of Measures under Consideration. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81172*.

Unmet patient needs resulting in admissions and ED visits related to chemotherapy treatment pose a heavy financial burden and affect patients' quality of life. Based on available commercial claims data, in 2010 the national average cost of a chemotherapy-related admission was $22,000, and the average cost of a chemotherapy-related ED visit was $800.[158] Furthermore, admissions and ED visits can reduce patients' quality of life by affecting their physical and emotional well-being, disrupting their schedules, decreasing their desire to engage in work and social activities, and increasing the burden on their family.[159] [160]

Hospital admissions and ED visits among cancer patients are often caused by manageable side effects. Chemotherapy treatment can have severe, predictable side effects. Recent studies of cancer outpatients show the most commonly cited symptoms and reasons for unplanned hospital visits following chemotherapy treatment are pain, anemia, fatigue, nausea and/or vomiting, fever and/or febrile neutropenia, shortness of breath, dehydration, diarrhea, and anxiety/depression.[161] These hospital visits may be due to conditions related to the cancer itself or to side effects of chemotherapy. However, treatment plans and guidelines exist to support the management of these conditions. PCHs that provide outpatient chemotherapy should implement appropriate care to minimize the need for acute hospital care for these adverse events. Guidelines from the American Society of Clinical Oncology, National Comprehensive Cancer Network, Oncology Nursing Society, Infectious Diseases Society of America, and other professional societies recommend evidence-based interventions to prevent and treat common side effects and complications of chemotherapy. Appropriate outpatient care should reduce potentially avoidable hospital admissions and ED visits for these issues and improve cancer patients' quality of life.

This measure aims to assess the care provided to cancer patients and encourage quality improvement efforts to reduce the number of unplanned inpatient admissions and ED visits among cancer patients receiving chemotherapy in a PCH outpatient setting. Improved PCH management of these potentially preventable symptoms—including anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—could reduce unplanned admissions and ED visits for these conditions. Measuring unplanned admissions and ED visits for cancer patients receiving outpatient chemotherapy would provide PCHs with an incentive to improve the quality of care for these patients by taking steps to prevent and better manage side effects and complications from treatment. In addition, this measure meets two National Quality Strategy priorities: (1) Promoting effective communication and coordination of care; and (2) promoting the most effective prevention and treatment practices for the leading causes of mortality.

We are proposing to adopt this measure under the exception authority in section 1866(k)(3)(B) of the Act under which, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization. Existing measures that the NQF has endorsed focus on processes of care related to outpatient cancer care.

This proposed measure aligns with the intent of two process measures we adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50842 through 50843) for FY 2016 and subsequent years: (1) Clinical Process/Oncology Care—Plan of Care for Pain (NQF #0383); and (2) Clinical Process/Oncology: Medical and Radiation—Pain Intensity Quantified (NQF #0384). Process measures NQF #0383 and NQF #0384, which are not risk-adjusted, support the intent of the proposed measure by reinforcing that providers of outpatient care should screen for and manage symptoms such as pain. The proposed measure improves upon these two measures in two key ways: (1) It does not target a specific symptom, but rather assesses the overall management of 10 important symptoms that studies have identified as frequent reasons for ED visits and inpatient admissions in this population; and (2) it assesses the care outcomes that matter to patients, rather than measuring processes to detect and treat these conditions. Also, we are not aware of any other measures a consensus organization has endorsed or adopted that assess the quality of outpatient cancer care by measuring unplanned inpatient admissions and ED visits.

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[150] American Cancer Society. "Cancer Facts & Figures 2015." Available at: *http://www.cancer.org/acs/groups/content/@editorial/documents/document/acspc-044552.pdf.*

[151] Klodziej, M., J.R. Hoverman, J.S. Garey, J. Espirito, S. Sheth, A. Ginsburg, M.A. Neubauer, D. Patt, B. Brooks, C. White, M. Sitarik, R. Anderson, and R. Beveridgel. "Benchmarks for Value in Cancer Care: An Analysis of a Large Commercial Population." *Journal of Oncology Practice,* Vol. 7, 2011, pp. 301–306.

[152] Sockdale, H., K. Guillory. "Lifeline: Why Cancer Patients Depend on Medicare for Critical Coverage." Available at: *http://www.acscan.org/content/wp-content/uploads/2013/06/2013-Medicare-Chartbook-Online-Version.pdf.*

[153] Vandervelde, Aaron, Henry Miller, and JoAnna Younts. "Impact on Medicare Payments of Shift in Site of Care for Chemotherapy Administration." Washington, DC: Berkeley Research Group, June 2014. Available at: *http://www.communityoncology.org/UserFiles/BRG_340B_SiteofCare_ReportF_6–9–14.pdf.*

[154] McKenzie, H., L. Hayes, K. White, K. Cox, J. Fethney, M. Boughton, and J. Dunn. "Chemotherapy Outpatients' Unplanned Presentations to Hospital: A Retrospective Study." *Supportive Care in Cancer,* Vol. 19, No. 7, 2011, pp. 963–969.

[155] Sadik, M., K. Ozlem, M. Huseyin, B. AliAyberk, S. Ahmet, and O. Ozgur. "Attributes of Cancer Patients Admitted to the Emergency Department in One Year." *World Journal of Emergency Medicine,* Vol. 5, No. 2, 2014, pp. 85–90. Available at: *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4129880/#ref4.*

[156] Hassett, M.J., J. O'Malley, J.R. Pakes, J.P. Newhouse, and C.C. Earle. "Frequency and Cost of Chemotherapy-Related Serious Adverse Effects in a Population Sample of Women with Breast Cancer." *Journal of the National Cancer Institute,* Vol. 98, No. 16, 2006, pp. 1108–1117.

[157] Foltran, L., G. Aprile, F.E. Pisa, P. Ermacora, N. Pella, E. Iaiza, E. Poletto, SE. Lutrino, M. Mazzer, M. Giovannoni, G.G. Cardellino, F. Puglisi, and G. Fasola. "Risk of Unplanned Visits for Colorectal Cancer Outpatients Receiving Chemotherapy: A Case-Crossover Study." *Supportive Care in Cancer,* Vol. 22, No. 9, 2014, pp. 2527–2533.

[158] Fitch, K., and B. Pyenson. "Cancer Patients Receiving Chemotherapy: Opportunities for Better Management." Available at: *http://us.milliman.com/uploadedFiles/insight/research/health-rr/cancer-patients-receiving-chemotherapy.pdf.*

[159] McKenzie, H., L. Hayes, K. White, K. Cox, J. Fethney, M. Boughton, and J. Dunn. "Chemotherapy Outpatients' Unplanned Presentations to Hospital: A Retrospective Study." *Supportive Care in Cancer,* Vol. 19, No. 7, 2011, pp. 963–969.

[160] Hassett, M.J., J. O'Malley, J.R. Pakes, J.P. Newhouse, and C.C. Earle. "Frequency and Cost of Chemotherapy-Related Serious Adverse Effects in a Population Sample of Women with Breast Cancer." *Journal of the National Cancer Institute,* Vol. 98, No. 16, 2006, pp. 1108–1117.

[161] Ibid.

The MAP supported this measure on the condition that it is reviewed and endorsed by NQF. We refer readers to the Spreadsheet of MAP 2016 Final Recommendations available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593*. In particular, MAP members recommended considering the measure for sociodemographic status (SDS) adjustment in the ongoing NQF trial period and reviewing it to ensure that the detailed specifications meet the intent of the measure and align with current cancer care practice.

We understand the important role that SDS plays in the care of patients. However, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on hospitals' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model. We submitted this measure to NQF with appropriate consideration for SDS for endorsement proceedings as part of the NQF Cancer Consensus Development Project in March 2016 and it is currently undergoing review. However, the measure we are proposing to adopt at this time for the PCHQR Program does not include this adjustment.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the effect of socioeconomic, demographic, and other characteristics on quality measures, resource use, and other measures in the Medicare program, as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

In addition, several MAP members noted the alignment of this measure concept with other national priorities, such as improving patient experience, and other national initiatives to improve cancer care, as well as the importance of this measure to raise awareness and create a feedback loop with providers.

This Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy measure is a risk-standardized outcome measure for patients age 18 years or older who are receiving PCH-based outpatient chemotherapy treatment for all cancer types except leukemia; it measures inpatient admissions or ED visits within 30 days of each outpatient chemotherapy encounter for any of the following qualifying diagnoses: anemia, dehydration; diarrhea; emesis; fever; nausea; neutropenia; pain; pneumonia; or sepsis, as these are associated with commonly cited reasons for hospital visits among cancer patients receiving chemotherapy.[162]

The proposed measure uses 1 year of Medicare FFS Part A and Part B administrative claims data with respect to beneficiaries receiving chemotherapy treatment in a PCH outpatient setting. The qualifying diagnosis on the admission or ED visit claim must be (1) the primary diagnosis or (2) a secondary diagnosis accompanied by a primary diagnosis of cancer.

We limited the window for identifying the outcomes of admissions and ED visits to 30 days after PCH outpatient chemotherapy treatment encounters, as existing literature suggests the vast majority of adverse events occur within that time frame [163] [164] [165] and we also observed this during testing. In addition, the technical expert panel (TEP) supported this time window because: (1) It helps link patients' experiences to the facilities that provided their recent treatment while accounting for variations in time between outpatient treatment encounters; (2) it supports the idea that the admission is related to the management of side effects of treatment and ongoing care, as opposed to progression of the disease or other unrelated events; and (3) clinically, 30 days after each outpatient chemotherapy treatment is a reasonable timeframe to observe related side effects.

The measure identifies outcomes separately for the inpatient and ED measures. A patient can qualify only once for one of the two outcomes in each measurement period. If patients experience both an inpatient admission and an ED visit after outpatient chemotherapy during the measurement period, the measure counts them toward the inpatient admission outcome because this outcome represents a more significant deterioration in patient quality of life, and is more costly. Among those with no qualifying inpatient admissions, the measure counts qualifying standalone ED visits. As a result, the rates provide a comprehensive performance estimate of quality of care. We calculate the rates separately because the severity and cost of an inpatient admission differ from those of an ED visit, but both adverse events are significant quality indicators and represent outcomes of care that are important to patients.

The measure attributes the outcome to the PCH where the patient received chemotherapy treatment during the 30 days before the outcome. If a patient received outpatient chemotherapy treatment from more than one PCH in the 30 days before the outcome, the measure would attribute the outcome to all the PCHs that provided treatment. For example, if a patient received an outpatient chemotherapy treatment at PCH A on January 1, a second treatment at PCH B on January 10, and then experienced a qualifying inpatient admission on January 15, the measure would count this outcome for both PCH A and PCH B because both PCHs provided outpatient chemotherapy treatment to the patient within the 30-day window. However, if a patient received an outpatient chemotherapy treatment from PCH A on January 1, and a second treatment from PCH B on March 1, and then experienced a qualifying inpatient admission on March 3, the measure would attribute this outcome only to PCH B. In measure testing, using Medicare FFS claims data from July 1, 2012, to June 30, 2013, only 5 percent of patients in the cohort received outpatient chemotherapy treatment from more than one facility during that year.

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[162] Hassett, M.J., J. O'Malley, J.R. Pakes, J.P. Newhouse, and C.C. Earle. "Frequency and Cost of Chemotherapy-Related Serious Adverse Effects in a Population Sample of Women with Breast Cancer." *Journal of the National Cancer Institute*, Vol. 98, No. 16, 2006, pp. 1108–1117.

[163] Aprile, G., F.E. Pisa, A. Follador, L. Foltran, F. De Pauli, M. Mazzer, S. Lutrino, C.S. Sacco, M. Mansutti, and G. Fasola. "Unplanned Presentations of Cancer Outpatients: A Retrospective Cohort Study." *Supportive Care in Cancer*, Vol. 21, No. 2, 2013, pp. 397–404.

[164] Foltran, L., G. Aprile, F.E. Pisa, P. Ermacora, N. Pella, E. Iaiza, E. Poletto, SE. Lutrino, M. Mazzer, M. Giovannoni, G.G. Cardellino, F. Puglisi, and G. Fasola. "Risk of Unplanned Visits for Colorectal Cancer Outpatients Receiving Chemotherapy: A Case-Crossover Study." *Supportive Care in Cancer*, Vol. 22, No. 9, 2014, pp. 2527–2533.

[165] McKenzie, H., L. Hayes, K. White, K. Cox, J. Fethney, M. Boughton, and J. Dunn. "Chemotherapy Outpatients' Unplanned Presentations to Hospital: A Retrospective Study." *Supportive Care in Cancer*, Vol. 19, No. 7, 2011, pp. 963–969.

For additional methodology details, including the code sets used to identify the qualifying outcomes, we refer readers to the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html* under "Hospital Outpatient Chemotherapy."

This measure includes all adult Medicare FFS patients because this would enable us to more broadly assess the quality of care provided by the PCH.

This measure focuses on treatments in the PCH outpatient setting because of the increase in hospital-based chemotherapy, which presents an opportunity to coordinate care. From 2008 to 2012, the proportion of Medicare patients receiving hospital-based outpatient chemotherapy increased from 18 to 29 percent, and this trend is likely to continue. As currently specified, the measure identifies chemotherapy treatment using ICD–9–CM procedure and encounter codes and Current Procedural Terminology (CPT)/Healthcare Common Procedure Coding System (HCPCS) procedure and medication procedure codes. It excludes procedure codes for oral chemotherapy because it is challenging to identify oral chemotherapy without using pharmacy claims data and, according to our TEP, most oral chemotherapies have fewer adverse reactions that result in admissions. We have developed a "coding crosswalk" between the ICD–9–CM codes and the ICD–10 codes that became effective beginning on October 1, 2015, and we will test this crosswalk prior to implementation. For detailed information on the cohort definition, including the ICD–9–CM, ICD–10, CPT, and HCPCS codes that identify chemotherapy treatment, we refer readers to the Data Dictionary appendix to the measure Technical Report at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html* under "Hospital Outpatient Chemotherapy."

The measure excludes three groups of patients: (1) Patients with a diagnosis of leukemia at any time during the measurement period because of the high toxicity of treatment and recurrence of disease, and because inpatient admissions and ED visits may reflect a relapse, rather than poorly managed outpatient care; (2) patients who were not enrolled in Medicare FFS Parts A and B in the year before the first outpatient chemotherapy treatment encounter during the measurement period (because the risk-adjustment model uses claims data for the year before the first chemotherapy treatment encounter during the period to identify comorbidities); and (3) patients who do not have at least one outpatient chemotherapy treatment encounter followed by continuous enrollment in Medicare FFS Parts A and B in the 30 days after the encounter (because the measure cannot assess the 30-day outcome in this group since it uses claims data to determine whether a patient had an ED visit or a hospital inpatient admission).

Risk adjustment takes into account important demographic and clinically-relevant patient characteristics that have strong relationships with the outcome. It seeks to adjust for differences in patient demographics, clinical comorbidities, and treatment exposure, which vary across patient populations and influence the outcome but do not relate to quality. Specifically, the measure adjusts for: (1) The patient's age at the start of the measurement period; (2) sex; (3) comorbidities that convey information about the patient in the 12 months before his or her first outpatient chemotherapy treatment encounter during the measurement period; (4) cancer type; and (5) the number of outpatient chemotherapy treatments the patient received at the reporting PCH during the measurement period.

We developed two risk-adjustment models, one for each dependent variable described above—qualifying inpatient admissions and qualifying ED visits. The separate models are necessary to enable the use of the most parsimonious model with variables tailored to those that are most predictive for each of the measure's two mutually exclusive outcomes. The measure algorithm first searches for a qualifying inpatient admission, and for those patients that do not have a qualifying inpatient admission, searches for a qualifying ED visit. Therefore, the patient-mix and predictive risk factors for each outcome is slightly different. The statistical risk-adjustment model for inpatient admissions includes 20 clinically relevant risk-adjustment variables that are strongly associated with the risk of one or more hospital admissions within 30 days following an outpatient chemotherapy treatment encounter in a hospital outpatient setting; the statistical risk-adjustment model for ED visits includes 15 clinically relevant risk-adjustment variables that are strongly associated with risk of one or more ED visits within 30 days following an outpatient chemotherapy treatment encounter in a hospital outpatient setting (3 comorbidities and 2 cancer types significant for inpatient admissions are not significant for ED visits).

The measure uses hierarchical logistic modeling, similar to the approach used in the CMS inpatient hospital 30-day risk-standardized mortality and readmission outcome measures, such as the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization.[166] This approach appropriately accounts for both differences in patient-mix and the clustering of observations within PCHs. The measure calculates the PCH-specific risk-adjusted rate as the ratio of the PCH's "predicted" number of outcomes to "expected" number of outcomes multiplied by the national observed outcome rate. It estimates the expected number of outcomes for each PCH using the PCH's patient-mix and the average PCH-specific intercept (that is, the average intercept among all PCHs in the sample). The measure estimates the predicted number of outcomes for each PCH using the same patient-mix, but an estimated PCH-specific intercept.

The measure calculates two rates, one for each mutually exclusive outcome (qualifying inpatient admissions and qualifying ED visits). It derives the two rates (also referred to as the PCH-level risk-standardized admission rate (RSAR) and risk-standardized ED visit rate (RSEDR)), from the ratio of the numerator to the denominator multiplied by the national observed rate. The numerator is the number of predicted (meaning adjusted actual) patients with the measured adverse outcome. The denominator is the number of patients with the measured adverse outcome the PCH is expected to have based on the national performance with the PCH's case mix. The national observed rate is the national unadjusted number of patients who have an adverse outcome among all the qualifying patients who had at least one chemotherapy treatment encounter in a PCH. If the "predicted" number of outcomes is higher (or lower) than the "expected" number of outcomes for a given hospital, the risk-standardized rate will be higher (or lower) than the national observed rate.

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[166] Methodology reports for these measures are available at the following link: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

For more detailed information on the calculation methodology, we refer readers to the methodology report at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html* under "Hospital Outpatient Chemotherapy."

We would publicly report the RSAR and RSEDR for all participating PCHs with 25 or more eligible patients per measurement period to maintain a reliability of at least 0.4 (as measured by the interclass correlation coefficient, ICC). If a PCH does not meet the 25 eligible patient threshold, we would include a footnote on the *Hospital Compare* Web site indicating that the number of cases is too small to reliably measure that PCH's rate. These patients and PCHs would still be included when calculating the national rates for both the RSAR and RSEDR.

To prepare PCHs for public reporting, we would conduct a confidential national reporting (dry run) of measure results prior to public reporting. The objectives of the dry run are to: (1) Educate PCHs and other stakeholders about the measure; (2) allow PCHs to review their measure results and data prior to public reporting; (3) answer questions from PCHs and other stakeholders; (4) test the production and reporting process; and (5) identify potential technical changes to the measure specifications that might be needed. We have not yet determined the measurement period to use for the dry run calculations, but acknowledge the importance of including some data based on ICD–10 codes to evaluate the success of the "coding crosswalk."

We are inviting public comment on our proposal to adopt the Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy measure for the FY 2019 program year and subsequent years.

In summary, the previously finalized and newly proposed measures for the PCHQR Program for the FY 2019 program year and subsequent years are listed in the table below.

PREVIOUSLY FINALIZED AND PROPOSED PCHQR MEASURES FOR THE FY 2019 PROGRAM YEAR AND SUBSEQUENT YEARS

Short name	NQF No.	Measure name
Safety and Healthcare-Associated Infection (HAI)		
CLABSI	0139	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection Outcome Measure.
CAUTI	0138	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infections Outcome Measure.
SSI	0753	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery].
CDI	1717	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.
MRSA	1716	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* Bacteremia Outcome Measure.
HCP	0431	Influenza Vaccination Coverage Among Healthcare Personnel.
Clinical Process/Cancer Specific Treatment		
N/A	0223	Adjuvant Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis to Patients Under the Age of 80 with AJCC III (lymph node positive) Colon Cancer.
N/A	0559	Combination Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis for Women Under 70 with AJCC T1cN0M0, or Stage IB—III Hormone Receptor Negative Breast Cancer. ***
N/A	0220	Adjuvant Hormonal Therapy.
Clinical Process/Oncology Care Measures		
N/A	0382	Oncology: Radiation Dose Limits to Normal Tissues. *
N/A	0383	Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology.
N/A	0384	Oncology: Medical and Radiation—Pain Intensity Quantified.
N/A	0390	Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Prostate Cancer Patients.
N/A	0389	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients.
Patient Engagement/Experience of Care		
HCAHPS	0166	HCAHPS.
Clinical Effectiveness Measure		
EBRT	1822	External Beam Radiotherapy for Bone Metastases.

PREVIOUSLY FINALIZED AND PROPOSED PCHQR MEASURES FOR THE FY 2019 PROGRAM YEAR AND SUBSEQUENT YEARS—Continued

Short name	NQF No.	Measure name
		Claims Based Outcome Measure
N/A	N/A	Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy. **

*Proposed for update in FY 2019 program year.

**Newly proposed for FY 2019 program year.

***In previous final rules, this measure was titled "Combination Chemotherapy is Considered or Administered Within 4 months (120 days) of Diagnosis for Women Under 70 with AJCC T1c, or Stage II or III Hormones Receptor Negative Breast Cancer. This name change is consistent with NQF updates to the measure name and reflects an update in the AJCC staging, does not reflect a change in the measure inclusion criteria, and is not considered substantive.

5. Possible New Quality Measure Topics for Future Years

We discussed future quality measure topics and quality measure domain areas in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50280), and in the FY 2016 IPPS/LTCH PPS final rule (80 FR4979), we discussed public comment and specific suggestions for measure topics addressing the following CMS Quality Strategy domains: Making care affordable; communication and coordination; and working with communities to promote best practices of healthy living. We welcome public comment and specific suggestions for measure topics that we should consider for future rulemaking.

6. Maintenance of Technical Specifications for Quality Measures

We maintain technical specifications for the PCHQR Program measures, and we periodically update those specifications. The specifications may be found on the QualityNet Web site at: *https://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228774479863.*

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50281), we adopted a policy under which we use a subregulatory process to make nonsubstantive updates to measures used for the PCHQR Program. We are not proposing any changes to this policy in this proposed rule.

7. Public Display Requirements

a. Background

Under section 1866(k)(4) of the Act, we are required to establish procedures for making the data submitted under the PCHQR Program available to the public. Such procedures must ensure that a PCH has the opportunity to review the data that are to be made public with respect to the PCH prior to such data being made public. Section 1866(k)(4) of the Act also provides that the Secretary must report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished in such hospitals on the CMS Web site. The measures that we have finalized for public display are shown in the table below.

PREVIOUSLY FINALIZED MEASURES FOR PUBLIC DISPLAY

Measure name	First year of public display
• Adjuvant Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis to Patients Under the Age of 80 with AJCC III (lymph node positive) Colon Cancer (NQF #0223).	2014
• Combination Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis for Women Under 70 with AJCC T1c, or Stage II or III Hormone Receptor Negative Breast Cancer (NQF #0559).	
• Adjuvant Hormonal Therapy (NQF #0220)	2015
• Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382)	2016
• Oncology: Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology (NQF #0383).	
• Oncology: Oncology: Medical and Radiation—Pain Intensity Quantified (NQF #0384).	
• Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Prostate Cancer Patients (NQF #0390).	
• Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients (NQF #0389).	
• HCAHPS (NQF #0166).	
• CLABSI (NQF #0139)	No Later Than 2017.
• CAUTI (NQF #0138).	

b. Proposed Additional Public Display Requirements

As we strive to publicly display data as soon as possible on a CMS Web site, we are proposing the following update to our public display polices. We believe it is best to not specify in rulemaking the exact timeframe during the year for publication as doing so may prevent earlier publication. We are proposing, then, to make these data available as soon as it is feasible during the year, starting with the first year for which we are publishing data for each measure. We will continue to propose in rulemaking the first year for which we intend to publish data for each measure. We intend to make the data available on at least a yearly basis.

As stated above, we are required to give PCHs an opportunity to review their data before the data are made public. Because we are proposing to make the data for this program available as soon as possible, and the timeframe for this publication may change year-to-year, we are not proposing to specify in rulemaking the exact dates for review. However, we are proposing that the time period for review would be approximately 30 days in length. We are proposing to announce the exact timeframes on a CMS Web site and/or on our applicable listservs.

We welcome public comments on these updates to our public display and preview policies.

c. Proposed Public Display of Additional PCHQR Measure

We are proposing to publicly display one additional PCHQR measure beginning with FY 2017 program year data (which is data collected during CY 2015). This proposal would mean that we would display the measure data during CY 2017, and that we would use a CMS Web site and/or our applicable listservs to announce the exact timeframe. This measure is External Beam Radiotherapy for Bone Metastases (NQF #1822), which we adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50278 through 50280). We believe that it is important to share data collected under the PCHQR Program with healthcare consumers through publication on public Web sites to help inform healthcare choices. We intend to make this data publicly available at the first opportunity.

We welcome public comment on our proposal to display this measure beginning with the FY 2017 program year data and for subsequent years.

d. Proposed Public Display of Updated Measure

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49720 through 49722), we finalized public display of the Oncology: Radiation Dose Limits to Normal Tissues measure in 2016 and subsequent years. If our proposal to update this measure (described in section VIII.B.3.b. of the preamble of this proposed rule) is finalized, we are proposing to begin displaying on *Hospital Compare* data using the updated measure cohort as soon as feasible after the updated data is collected in CY 2017. We intend to denote the cohort expansion on *Hospital Compare* to ensure that consumers are informed about the expansion.

We welcome public comment on our proposals regarding public display of this updated measure.

e. Proposed Postponement of Public Display of Two Measures

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50281 through 50282), we finalized public display of the CLABSI and CAUTI measures beginning no later than 2017 and subsequent years. However, at this time, we are proposing to defer the public reporting of these two measures' data. At present, all PCHs are reporting CLABSI and CAUTI data to the NHSN under the PCHQR Program; however, due to the low volume of data produced and reported by this small number of facilities, we need additional time to work with CDC to identify an appropriate timeframe for public reporting and collaborate on the analytic methods that will be used to summarize the CLABSI and CAUTI data for public reporting purposes.

We are inviting public comment on our proposal to defer the public reporting of the CLABSI and the CAUTI measures.

Our previously finalized and proposed public display requirements are summarized in the table below.

PREVIOUSLY FINALIZED AND PROPOSED PUBLIC DISPLAY REQUIREMENTS

Measures	Public reporting
Summary of Finalized and Proposed Public Display Requirements	
• Adjuvant Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis to Patients Under the Age of 80 with AJCC III (lymph node positive) Colon Cancer (NQF #0223).	2014 and subsequent years.
• Combination Chemotherapy is Considered or Administered Within 4 Months (120 days) of Diagnosis for Women Under 70 with AJCC T1cN0M0, or Stage IB—III Hormone Receptor Negative Breast Cancer (NQF #0559).	
• Adjuvant Hormonal Therapy (NQF #0220)	2015 and subsequent years.
• Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382).*	
• Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology (NQF #0383).	
• Oncology: Medical and Radiation—Pain Intensity Quantified (NQF #0384)	2016 and subsequent years.
• Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Prostate Cancer Patients (NQF #0390).	
• Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients (NQF #0389).	
• HCAHPS (NQF #0166).	
• CLABSI (NQF #0139).**	
• CAUTI (NQF #0138)**	Deferred.
• External Beam Radiotherapy for Bone Metastases (NQF #1822)***	Beginning at the first opportunity in 2017 and for subsequent years.

* Update proposed for display for the FY 2019 program year and subsequent years in this proposed rule—expanded cohort will be displayed as soon as feasible.

** Deferral proposed in this proposed rule.

*** Measure newly proposed for public display in this proposed rule.

8. Form, Manner, and Timing of Data Submission

Section 1866(k)(2) of the Act requires that, beginning with the FY 2014 PCHQR program year, each PCH must submit to the Secretary data on quality measures specified under section 1866(k)(3) of the Act in a form and manner, and at a time, as specified by the Secretary.

Data submission requirements and deadlines for the PCHQR Program are generally posted on the QualityNet Web site at: *http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772864228.*

The newly proposed measure for FY 2019 (Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy) is a claims-based measure; therefore, there are no additional data submission requirements for this measure. As this measure uses 1 year of Medicare administrative claims data, we are proposing to calculate this measure on a yearly basis, beginning with data from July 1, 2016 through June 30, 2017, and then to calculate the measure for subsequent years using data from July 1 through June 30.

We are not proposing any changes to previously finalized data submission requirements in this proposed rule.

9. Exceptions From PCHQR Program Requirements

In our experience with other quality reporting and performance programs, we have noted occasions when providers have been unable to submit required quality data due to extraordinary circumstances that are not within their control (for example, natural disasters). We do not wish to increase their burden unduly during these times. Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50848), we finalized our policy that, for the FY 2014 program rear and subsequent years, PCHs may request and we may grant exceptions (formerly referred to as waivers) with respect to the reporting of required quality data when extraordinary circumstances beyond the control of the PCH warrant. When exceptions are granted, we will notify the respective PCH.

We are not proposing any changes to this PCHQR exception process in this proposed rule.

C. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

1. Background and Statutory Authority

We seek to promote higher quality and more efficient health care for Medicare beneficiaries, and our efforts are furthered by quality reporting programs coupled with public reporting of that information.

Section 3004(a) of the Affordable Care Act amended section 1886(m)(5) of the Act, requiring the Secretary to establish the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). The LTCH QRP applies to all hospitals certified by Medicare as LTCHs. Beginning with the FY 2014 payment determination and subsequent years, the Secretary is required to reduce any annual update to the LTCH PPS standard Federal rate for discharges occurring during such fiscal year by 2 percentage points for any LTCH that does not comply with the requirements established by the Secretary. Section 1886(m)(5) of the Act requires that for the FY 2014 payment determination and subsequent years, each LTCH submit data on quality measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary. For more information on the statutory history of the LTCH QRP, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50286).

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) imposed new data reporting requirements for certain post-acute care (PAC) providers, including LTCHs. For information on the statutory background of the IMPACT Act, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49723 through 49724).

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49723 through 49728), we reviewed and finalized the activities and the timeline and sequencing of such activities that would occur under the LTCH QRP. In addition, we established our approach for identifying cross-cutting measures and process for the adoption of measures, including the application and purpose of the Measures Application Partnership (MAP) and the notice-and-comment rulemaking process. For information on these topics, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49723).

2. General Considerations Used for Selection of Quality, Resource Use, and Other Measures for the LTCH QRP

For a detailed discussion of the considerations we use for the selection of LTCH QRP quality measures, such as alignment with the CMS Quality Strategy,[167] which incorporates the three broad aims of the National Quality Strategy,[168] we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50286 through 50287) and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49728). Overall, we strive to promote high quality and efficiency in the delivery of health care to the beneficiaries we serve. Performance improvement leading to the highest quality health care requires continuous evaluation to identify and address performance gaps and reduce the unintended consequences that may arise in treating a large, vulnerable, and aging population. Quality reporting programs, coupled with public reporting of quality information, are critical to the advancement of health care quality improvement efforts. Valid, reliable, relevant quality measures are fundamental to the effectiveness of our quality reporting programs. Therefore, selection of quality measures is a priority for CMS in all of its quality reporting programs.

In this proposed rule, we are proposing to adopt for the LTCH QRP one measure that we are specifying under section 1899B(c)(1) of the Act to meet the Medication Reconciliation domain, that is, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP. Further, we are proposing for the LTCH QRP to adopt three measures in order to meet the resource use and other measure domains identified in section 1899B(d)(1) of the Act. These measures consist of: (1) Total Estimated Medicare Spending Per Beneficiary (MSPB): MSPB–PAC LTCH QRP; (2) Discharge to Community: Discharge to Community-PAC LTCH QRP; and (3) Measures to reflect all-condition risk-adjusted potentially preventable hospital readmission rates: Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP.

In our selection and specification of measures, we employ a transparent process in which we seek input from stakeholders and national experts and engage in a process that allows for pre-rulemaking input on each measure, as required by section 1890A of the Act. To meet this requirement, we provided the following opportunities for stakeholder input: Our measure development contractor convened technical expert panels (TEPs) that included stakeholder experts and patient representatives on July 29, 2015, for the Drug Regimen Review Conducted with Follow-Up for Identified Issues measures; on August 25, 2015, September 25, 2015, and October 5, 2015, for the Discharge to Community measures; on August 12 and 13, 2015, and October 14, 2015 for the Potentially Preventable 30-Day Post-Discharge Readmission Measures; and on October 29 and 30, 2015, for the Medicare Spending Per Beneficiary measures. In addition, we released draft quality measure specifications for public comment for the Drug Regimen Review Conducted with Follow-Up for Identified Issues measures from September 18, 2015, to October 6, 2015; for the Discharge to Community measures from November 9, 2015, to December 8, 2015; for the Potentially Preventable 30-Day Post-Discharge Readmission Measures from November 2, 2015 to December 1, 2015; and for the Medicare Spending Per Beneficiary measures from January 13, 2016 to February 5, 2016. We implemented a public mailbox, *PACQualityInitiative@cms.hhs.gov*, for the submission of public comments. This PAC mailbox is accessible on our post-acute care quality initiatives Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-*

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[167] *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html.*

[168] *http://www.ahrq.gov/workingforquality/nqs/nqs2011annlrpt.htm.*

Act-of-2014-and-Cross-Setting-Measures.html.

In addition, we sought public input from the MAP Post-Acute Care, Long-Term Care Workgroup during the annual in-person meeting held December 14 and 15, 2015. The MAP is composed of multi-stakeholder groups convened by the NQF, our current contractor under section 1890(a) of the Act, tasked to provide input on the selection of quality and efficiency measures described in section 1890(b)(7)(B) of the Act.

The MAP reviewed each IMPACT Act-related measure proposed in this proposed rule for use in the LTCH QRP. For more information on the MAP's recommendations, we refer readers to the MAP 2016 Final Recommendations to HHS and CMS public report at: *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.*

For measures that do not have NQF endorsement, or which are not fully supported by the MAP for use in the LTCH QRP, we are proposing for the LTCH QRP for the purposes of satisfying the measure domains required under the IMPACT Act measures that closely align with the national priorities identified in the National Quality Strategy (*http://www.ahrq.gov/workingforquality/*) and for which the MAP supports the measure concept. Further, discussion as to the importance and high-priority status of these proposed measures in the LTCH setting is included under each quality measure proposal in this proposed rule.

3. Policy for Retention of LTCH QRP Measures Adopted for Previous Payment Determinations

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53614 through 53615), for the purpose of streamlining the rulemaking process, we adopted a policy that, when we initially adopt a measure for the LTCH QRP for a payment determination and all subsequent years, it would remain in effect until the measure was actively removed, suspended, or replaced. For further information on how measures are considered for removal, suspension, or replacement, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53614 through 53615).

We are not proposing any changes to the policy for retaining LTCH QRP measures adopted for previous payment determinations.

4. Policy for Adopting Changes to LTCH QRP Measures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53615 through 53616), we adopted a subregulatory process to incorporate NQF updates to LTCH quality measure specifications that do not substantively change the nature of the measure. Substantive changes will be proposed and finalized through rulemaking. For further information on what constitutes a substantive versus a nonsubstantive change and the subregulatory process for nonsubstantive changes, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53615 through 53616). We are not proposing any changes to the policy for adopting changes to LTCH QRP measures.

5. Quality Measures Previously Finalized for and Currently Used in the LTCH QRP

A history of the LTCH QRP quality measures adopted for the FY 2014 payment determinations and subsequent years is presented in the table below. The year in which each quality measure was first adopted and implemented, and then subsequently readopted or revised, if applicable, is displayed. The initial and subsequent annual payment determination years are also shown in this table. For more information on a particular measure, we refer readers to the IPPS/LTCH PPS final rule and associated page numbers referenced in this table.

QUALITY MEASURES PREVIOUSLY FINALIZED FOR AND CURRENTLY USED IN THE LTCH QRP

Measure title	IPPS/LTCH PPS Final rule	Data collection start date	Annual payment determination: initial and subsequent APU Years
National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138).	Adopted an application of the measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51745 through 51747).	October 1, 2012	FY 2014 and subsequent years.
	Adopted the NQF-endorsed version and expanded measure (with standardized infection ratio [SIR]) in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53616 through 53619).	January 1, 2013	FY 2015 and subsequent years.
National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139).	Adopted an application of the measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51747 through 51748).	October 1, 2012	FY 2014 and subsequent years.
	Adopted the NQF-endorsed and expanded measure (with SIR) in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53616 through 53619).	January 1, 2013	FY 2015 and subsequent years.
Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678).	Adopted an application of the measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51748 through 51750).	October 1, 2012	FY 2014 and subsequent years.
	Adopted the NQF-endorsed version in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50861 through 50863).	January 1, 2013	FY 2015 and subsequent years.
	Adopted in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49731 through 49736) to fulfill IMPACT Act requirements.	January 1, 2016	FY 2018 and subsequent years.

Quality Measures Previously Finalized for and Currently Used in the LTCH QRP—Continued

Measure title	IPPS/LTCH PPS Final rule	Data collection start date	Annual payment determination: initial and subsequent APU Years
Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680).	Adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53624 through 53627).	January 1, 2014	FY 2016 and subsequent years.
	Revised data collection timeframe in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50858 through 50861).	October 1, 2014	FY 2016 and subsequent years.
	Revised data collection timeframe in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50289 through 50290).	October 1, 2014	FY 2016 and subsequent years.
Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431).	Adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53630 through 53631).	October 1, 2014	FY 2016 and subsequent years.
	Revised data collection timeframe in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50857 through 50858).	October 1, 2014	FY 2016 and subsequent years.
All-Cause Unplanned Readmission Measure for 30-Days Post-Discharge from Long-Term Care Hospitals (NQF #2512).	Adopted in FY 2014 IPPS/LTCH PPS final rule (78 FR 50868 through 50874).	N/A	FY 2017 and subsequent years.
	Adopted the NQF-endorsed version in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49730 through 49731).	N/A	FY 2018 and subsequent years.
National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716).	Adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50863 through 50865).	January 1, 2015	FY 2017 and subsequent years.
National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717).	Adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50865 through 50868).	January 1, 2015	FY 2017 and subsequent years.
National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure (NQF #N/A).	Adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50301 through 50305).	January 1, 2016	FY 2018 and subsequent years.
Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).	Adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50874 through 50877).	January 1, 2016	FY 2018 and subsequent years.
	Revised data collection timeframe in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50290 through 50291).	April 1, 2016	FY 2018 and subsequent years.
	Adopted an application of the measure in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49736 through 49739) to fulfill IMPACT Act requirements.	April 1, 2016	FY 2018 and subsequent years.
Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).	Adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50291 through 50298).	April 1, 2016	FY 2018 and subsequent years.
Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).	Adopted an application of the measure in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49739 through 49747) to fulfill IMPACT Act requirements.	April 1, 2016	FY 2018 and subsequent years.
Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632).	Adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50298 through 50301).	April 1, 2016	FY 2018 and subsequent years.

6. LTCH QRP Quality, Resource Use and Other Measures Proposed for the FY 2018 Payment Determination and Subsequent Years

For the FY 2018 payment determinations and subsequent years, in addition to the quality measures we are retaining under our policy described in section VIII.C.3. of the preamble of this proposed rule, we are proposing three new measures. These measures were developed to meet the requirements of the IMPACT Act. They are:

- MSPB–PAC LTCH QRP;
- Discharge to Community-PAC LTCH QRP, and
- Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP.

The measures are described in more detail below.

For the risk-adjustment of the resource use and other measures, we understand the important role that sociodemographic status plays in the care of patients. However, we continue to have concerns about holding providers to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on providers' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

We are inviting public comment on how socioeconomic and demographic factors should be used in risk adjustment for the resource use measures.

a. Proposal To Address the IMPACT Act Domain of Resource Use and Other Measures: Total Estimated MSPB–PAC LTCH QRP

We are proposing an MSPB–PAC LTCH QRP measure for inclusion in the LTCH QRP for the FY 2018 payment determination and subsequent years. Section 1899B(d)(1)(A) of the Act requires the Secretary to specify resource use measures, including total estimated Medicare spending per beneficiary, on which PAC providers, consisting of LTCHs, Inpatient Rehabilitation Facilities (IRFs), Skilled Nursing Facilities (SNFs), and Home Health Agencies (HHAs), are required to submit necessary data specified by the Secretary.

Rising Medicare expenditures for post-acute care as well as wide variation in spending for these services underlines the importance of measuring resource use for providers rendering these services. Between 2001 and 2013, Medicare PAC spending grew at an annual rate of 6.1 percent and doubled to $59.4 billion, while payments to inpatient hospitals grew at an annual rate of 1.7 percent over this same period.[169] A study commissioned by the Institute of Medicine found that variation in PAC spending explains 73 percent of variation in total Medicare spending across the United States.[170]

We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed resource use measures for PAC settings. Therefore, we are proposing this MSPB–PAC LTCH QRP measure under the Secretary's authority to specify non-NQF-endorsed measures under section 1899B(e)(2)(B) of the Act. Because of the current lack of resource use measures for PAC settings, our proposed MSPB–PAC LTCH QRP measure has the potential to provide valuable information to LTCHs on their relative Medicare spending in delivering services to approximately 122,000 Medicare beneficiaries.[171]

The proposed MSPB–PAC LTCH QRP episode-based measure will provide actionable and transparent information to support LTCHs' efforts to promote care coordination and deliver high quality care at a lower cost to Medicare. The MSPB–PAC LTCH QRP measure holds LTCHs accountable for the Medicare payments within an "episode of care" (episode), which includes the period during which a patient is directly under the LTCH's care, as well as a defined period after the end of the LTCH treatment, which may be reflective of and influenced by the services furnished by the LTCH. MSPB–PAC LTCH QRP episodes, constructed according to the methodology described below, have high levels of Medicare spending with substantial variation. In FY 2013 and FY 2014, Medicare FFS beneficiaries experienced 178,538 MSPB–PAC LTCH QRP episodes triggered by admission to an LTCH. The mean payment-standardized, risk-adjusted episode spending for these episodes is $67,181. There is substantial variation in the Medicare payments for these MSPB–PAC LTCH QRP episodes—ranging from approximately $27,502 at the 5th percentile to approximately $115,291 at the 95th percentile. This variation is partially driven by variation in payments occurring following LTCH treatment.

Evaluating Medicare payments during an episode creates a continuum of accountability between providers and has the potential to improve post-treatment care planning and coordination. While some stakeholders throughout the measure development process supported the measures and believed that measuring Medicare spending was critical for improving efficiency, other stakeholders believed that resource use measures did not reflect quality of care in that they do not take into account patient outcomes or experience beyond those observable in claims data. However, LTCHs involved in the provision of high quality PAC care as well as appropriate discharge planning and post-discharge care coordination would be expected to perform well on this measure since beneficiaries would likely experience fewer costly adverse events (for example, avoidable hospitalizations, infections, and emergency room usage). Further, it is important that the cost of care be explicitly measured so that, in conjunction with other quality measures, we can recognize providers that are involved in the provision of high quality care at lower cost.

We have undertaken development of MSPB–PAC measures for each of the four PAC settings. We intend to propose IRF-, SNF-, and HHA-specific MSBP–PAC measures through future notice-and-comment rulemaking. The four setting-specific MSPB–PAC measures are closely aligned in terms of episode construction and measure calculation. Each of the MSPB–PAC measures assess Medicare Part A and Part B spending during an episode, and the numerator and denominator are defined similarly for each of the MSPB–PAC measures. However, developing setting-specific measures allows us to account for differences between settings in payment policy, the types of data available, and the underlying health characteristics of beneficiaries. For example, the MSPB–PAC LTCH QRP measure reflects the dual payment rate of the LTCH PPS by comparing episodes triggered by each payment rate case only with episodes of the same type, as detailed below.

The MSPB–PAC measures mirror the general construction of the Hospital IQR Program MSPB measure that was finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51618 through 51627). That measure was endorsed by the NQF on December 6, 2013, and has been used in the Hospital VBP Program (NQF #2158) since FY 2015.[172] The Hospital IQR Program MSPB measure was originally established under the authority of section 1886(o)(2)(B)(ii) of the Act. The hospital MSPB measure evaluates hospitals' Medicare spending relative to the Medicare spending for the national median hospital during a hospital MSPB episode. It assesses Medicare Part A and Part B payments for services performed by hospitals and other healthcare providers during a hospital MSPB episode, which is comprised of the periods immediately prior to, during, and following a patient's hospital stay.[173] [174]

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[169] MedPAC, "A Data Book: Health Care Spending and the Medicare Program," (2015). 114.

[170] Institute of Medicine, "Variation in Health Care Spending: Target Decision Making, Not Geography," (Washington, DC: National Academies 2013). 2.

[171] Figures for 2013. MedPAC, "Medicare Payment Policy," Report to the Congress (2015). xvii-xviii.

Similarly, the MSPB–PAC measures assess all Medicare Part A and Part B payments for FFS claims with a start date during the episode window (which, as discussed below, is the time period during which Medicare FFS Part A and Part B services are counted towards the MSPB–PAC LTCH QRP episode). However, there are differences between the MSPB–PAC measures, as proposed, and the hospital MSPB measure to reflect differences in payment policies and the nature of care provided in each PAC setting. For example, the MSPB–PAC measures exclude a limited set of services (for example, for clinically unrelated services) provided to a beneficiary during the episode window while the hospital MSPB measure does not exclude any services.[175]

MSPB–PAC episodes may begin within 30 days of discharge from an inpatient hospital as part of a patient's trajectory from an acute to a PAC setting. An LTCH stay beginning within 30 days of discharge from an inpatient hospital will therefore be included once in the hospital's MSPB measure, and once in the LTCH's MSPB–PAC measure. Aligning the hospital MSPB and MSPB–PAC measures in this way creates continuous accountability and aligns incentives to improve care planning and coordination across inpatient and PAC settings.

We have sought and considered the input of stakeholders throughout the measure development process for the MSPB–PAC measures. We convened a TEP consisting of 12 panelists with combined expertise in all of the PAC settings on October 29 and 30, 2015, in Baltimore, Maryland. A follow-up email survey was sent to TEP members on November 18, 2015, to which 7 responses were received by December 8, 2015. The MSPB–PAC TEP Summary Report is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Technical-Expert-Panel-on-Medicare-Spending-Per-Beneficiary.pdf.* The measures were also presented to the NQF MAP Post-Acute Care/Long-Term Care (PAC/LTC) Workgroup on December 15, 2015. As the MSPB–PAC measures were under development, there were three voting options for members: Encourage continued development, do not encourage further consideration, and insufficient information.[176] The MAP PAC/LTC Workgroup voted to "encourage continued development" for each of the MSPB–PAC measures.[177] The MAP PAC/LTC Workgroup's vote of "encourage continued development" was affirmed by the MAP Coordinating Committee on January 26, 2016.[178] The MAP's concerns about the MSPB–PAC measures, as outlined in their final report, "MAP 2016 Considerations for Implementing Measures in Federal Programs: Post-Acute Care and Long-Term Care," and Spreadsheet of Final Recommendations were taken into consideration during the measure development process and are discussed as part of our responses to public comments, described below.[179] [180]

Since the MAP's review and recommendation of continued development, CMS has continued to refine risk adjustment models and conduct measure testing for the IMPACT Act measures in compliance with the MAP's recommendations. The proposed IMPACT Act measures are both consistent with the information submitted to the MAP and support the scientific acceptability of these measures for use in quality reporting programs.

In addition, a public comment period, accompanied by draft measures specifications, was originally open from January 13 to 27, 2016 and twice extended to January 29 and February 5. A total of 45 comments on the MSPB–PAC measures were received during this comment period. The comments received also covered each of the MAP's concerns as outlined in their Final Recommendations.[181] The MSPB–PAC Public Comment Summary Report is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html* and contains the public comments (summarized and verbatim), along with our responses including statistical analyses. If finalized, the proposed MSPB–PAC LTCH QRP measure, along with the other MSPB–PAC measures, as applicable, will be submitted for NQF endorsement.

To calculate the MSPB–PAC LTCH QRP measure for each LTCH, we first define the construction of the MSPB–PAC LTCH QRP episode, including the length of the episode window as well as the services included in the episode. Next, we apply the methodology for the measure calculation. The specifications are discussed further below. More detailed specifications for the proposed MSPB–PAC measures, including the MSPB–PAC LTCH QRP measure in this proposed rule, are available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

(1) Episode Construction

An MSPB–PAC LTCH QRP episode begins at the episode trigger, which is defined as the patient's admission to an LTCH. This admitting facility is the attributed provider, for whom the

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[172] QualityNet, "Measure Methodology Reports: Medicare Spending Per Beneficiary (MSPB) Measure," (2015). *http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996.*

[173] QualityNet, "Measure Methodology Reports: Medicare Spending Per Beneficiary (MSPB) Measure," (2015). *http://www.qualitynet.org/dcs/ContentServer?pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996.*

[174] FY 2012 IPPS/LTCH PPS final rule (76 FR 51619).

[175] FY 2012 IPPS/LTCH PPS final rule (76 FR 51620).

[176] National Quality Forum, Measure Applications Partnership, "Process and Approach for MAP Pre-Rulemaking Deliberations, 2015–2016" (February 2016) *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81693.*

[177] National Quality Forum, Measure Applications Partnership Post-Acute Care/Long-Term Care Workgroup, "Meeting Transcript—Day 2 of 2" (December 15, 2015) 104–106 *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81470.*

[178] National Quality Forum, Measure Applications Partnership, "Meeting Transcript—Day 1 of 2" (January 26, 2016) 231–232 *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81637.*

[179] National Quality Forum, Measure Applications Partnership, "MAP 2016 Considerations for Implementing Measures in Federal Programs: Post-Acute Care and Long-Term Care" Final Report, (February 2016) *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.*

[180] National Quality Forum, Measure Applications Partnership, "Spreadsheet of MAP 2016 Final Recommendations" (February 1, 2016) *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593.*

[181] National Quality Forum, Measure Applications Partnership, "Spreadsheet of MAP 2016 Final Recommendations" (February 1, 2016) *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81593.*

MSPB–PAC LTCH QRP measure is calculated. The episode window is the time period during which Medicare FFS Part A and Part B services are counted towards the MSPB–PAC LTCH QRP episode. Because Medicare FFS claims are already reported to the Medicare program for payment purposes, LTCHs will not be required to report any additional data to CMS for calculation of this measure. Thus, there will be no additional data collection burden from the implementation of this measure.

Our proposed MSPB–PAC LTCH QRP episode construction methodology differentiates between episodes triggered by standard payment rate cases and site neutral payment rate cases, reflecting the LTCH dual-payment policy detailed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623). Standard and site neutral episodes would be compared only with standard and site neutral episodes respectively. Differences in episode construction between standard and site neutral episodes are noted below; they otherwise share the same definition.

The episode window is comprised of a treatment period and an associated services period. The treatment period begins at the trigger (that is, on the day of admission to the LTCH) and ends on the day of discharge from that LTCH. Readmissions to the same facility occurring within 7 or fewer days do not trigger a new episode, and instead are included in the treatment period of the original episode. When two sequential stays at the same LTCH occur within 7 or fewer days of one another, the treatment period ends on the day of discharge for the latest LTCH stay. The treatment period includes those services that are provided directly or reasonably managed by the LTCH that are directly related to the beneficiary's care plan. The associated services period is the time during which Medicare Part A and Part B services (with certain exclusions) are counted towards the episode. The associated services period begins at the episode trigger and ends 30 days after the end of the treatment period. The distinction between the treatment period and the associated services period is important because clinical exclusions of services may differ for each period.

Certain services are excluded from the MSPB–PAC LTCH QRP episodes because they are clinically unrelated to LTCH care, and/or because LTCHs may have limited influence over certain Medicare services delivered by other providers during the episode window. These limited service-level exclusions are not counted towards a given LTCH's Medicare spending to ensure that beneficiaries with certain conditions and complex care needs receive the necessary care. Certain services that have been determined by clinicians to be outside of the control of an LTCH include planned hospital admissions, management of certain preexisting chronic conditions (for example, dialysis for end-stage renal disease (ESRD), and enzyme treatments for genetic conditions), treatment for preexisting cancers, organ transplants, and preventive screenings (for example, colonoscopy and mammograms). Exclusion of such services from the MSPB–PAC LTCH QRP episode ensures that facilities do not have disincentives to treat patients with certain conditions or complex care needs.

An MSPB–PAC episode may begin during the associated services period of an MSPB–PAC LTCH QRP episode in the 30 days post-treatment. One possible scenario occurs where an LTCH discharges a beneficiary who is then admitted to a HHA within 30 days. The HHA claim would be included once as an associated service for the attributed provider of the first MSPB–PAC LTCH QRP episode and once as a treatment service for the attributed provider of the second MSPB–PAC HHA episode. As in the case of overlap between hospital and PAC episodes discussed earlier, this overlap is necessary to ensure continuous accountability between providers throughout a beneficiary's trajectory of care, as both providers share incentives to deliver high quality care at a lower cost to Medicare.

Even within the LTCH setting, one MSPB–PAC LTCH QRP episode may begin in the associated services period of another MSPB–PAC LTCH QRP episode in the 30 days post-treatment. The second LTCH claim would be included once as an associated service for the attributed LTCH of the first MSPB–PAC LTCH QRP episode and once as a treatment service for the attributed LTCH of the second MSPB–PAC LTCH QRP episode. Again, this ensures that LTCHs have the same incentives throughout both MSPB–PAC LTCH QRP episodes to deliver quality care and engage in patient-focused care planning and coordination. If the second MSPB–PAC LTCH QRP episode were excluded from the second LTCH's MSPB–PAC LTCH QRP measure, that LTCH would not share the same incentives as the first LTCH of the first MSPB–PAC LTCH QRP episode. The MSPB–PAC LTCH QRP measure is designed to benchmark the resource use of each attributed provider against what their spending is expected to be as predicted through risk adjustment. As discussed further below, the measure takes the ratio of observed spending to expected spending for each episode and then takes the average of those ratios across all of the attributed provider's episodes. The measure is not a simple sum of all costs across a provider's episodes, thus mitigating concerns about double counting.

(2) Measure Calculation

Medicare payments for Part A and Part B claims for services included in MSPB–PAC LTCH episodes, defined according to the methodology above, are used to calculate the MSPB–PAC LTCH QRP measure. Measure calculation involves determination of the episode exclusions, the approach for standardizing payments for geographic payment differences, the methodology for risk adjustment of episode spending to account for differences in patient case mix, and the specifications for the measure numerator and denominator. The measure calculation is performed separately for MSPB–PAC LTCH QRP standard and site neutral episodes to ensure that they are compared only to other standard and site neutral episodes, respectively. The final MSPB–PAC LTCH QRP measure would combine the two ratios to construct one LTCH score as described below.

(a) Exclusion Criteria

In addition to service-level exclusions that remove some payments from individual episodes, we exclude certain episodes in their entirety from the MSPB–PAC LTCH QRP measure to ensure that the MSPB–PAC LTCH QRP measure accurately reflects resource use and facilitates fair and meaningful comparisons between LTCHs. The proposed episode-level exclusions are as follows:

- Any episode that is triggered by an LTCH claim outside the 50 States, DC, Puerto Rico, and U.S. territories.
- Any episode where the claim(s) constituting the attributed LTCH's treatment have a standard allowed amount of zero or where the standard allowed amount cannot be calculated.
- Any episode in which a beneficiary is not enrolled in Medicare FFS for the entirety of a 90-day lookback period (that is, a 90-day period prior to the episode trigger) plus episode window (including where a beneficiary dies), or is enrolled in Part C for any part of the lookback period plus episode window.
- Any episode in which a beneficiary has a primary payer other than Medicare for any part of the 90-day lookback period plus episode window.
- Any episode where the claim(s) constituting the attributed LTCH's

treatment include at least one related condition code indicating that it is not a prospective payment system bill.

(b) Standardization and Risk Adjustment

Section 1899B(d)(2)(C) of the Act requires that the MSPB–PAC measures are adjusted for the factors described under section 1886(o)(2)(B)(ii) of the Act, which include adjustment for factors such as age, sex, race, severity of illness, and other factors that the Secretary determines appropriate. Medicare payments included in the proposed MSPB–PAC LTCH QRP measure are payment-standardized and risk-adjusted. Payment standardization removes sources of payment variation not directly related to clinical decisions and facilitates comparisons of resource use across geographic areas. We are proposing to use the same payment standardization methodology as that used in the NQF-endorsed hospital MSPB measure. This methodology removes geographic payment differences, such as wage index and geographic practice cost index (GPCI), incentive payment adjustments, and other add-on payments that support broader Medicare program goals including indirect graduate medical education (IME) and hospitals serving a disproportionate share of uninsured patients (DSH).[182]

Risk adjustment uses patient claims history to account for case-mix variation and other factors that affect resource use but are beyond the influence of the attributed LTCH. To assist with risk adjustment for MSPB–PAC LTCH QRP episodes, we create mutually exclusive and exhaustive clinical case-mix categories using the most recent institutional claim in the 60 days prior to the start of the MSPB–PAC LTCH QRP episode. The beneficiaries in these clinical case-mix categories have a greater degree of clinical similarity than the overall LTCH patient population, and allow us to more accurately estimate Medicare spending. Our proposed MSPB–PAC LTCH QRP model, adapted for the LTCH setting from the NQF-endorsed hospital MSPB measure, uses a regression framework with a 90-day hierarchical condition category (HCC) lookback period and covariates including the clinical case mix categories, MS–LTC–DRGs, HCC indicators, age brackets, indicators for originally disabled, ESRD enrollment, and long-term care status, and selected interactions of these covariates where sample size and predictive ability make them appropriate. We sought and considered public comment regarding the treatment of hospice services occurring within the MSPB–PAC LTCH QRP episode window. After consideration of the comments received, we are proposing to include the Medicare spending for hospice services but risk adjust for them, so that MSPB–PAC LTCH QRP episodes with hospice are compared to a benchmark reflecting other MSPB–PAC LTCH QRP episodes with hospice. We believe that this strikes a balance between the measure's intent of evaluating Medicare spending and ensuring that providers do not have incentives against the appropriate use of hospice services in a patient-centered continuum of care.

We understand the important role that sociodemographic status, beyond age, plays in the care of patients. However, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on hospitals' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the impact of sociodemographic status on quality measures, resource use, and other measures under the Medicare program as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

While we conducted analyses on the impact of age by sex on the performance of the MSPB–PAC LTCH QRP risk-adjustment model, we are not proposing to adjust the MSPB–PAC LTCH measure for socioeconomic and demographic factors at this time. As this MSPB–PAC LTCH QRP measure will be submitted for NQF endorsement, we prefer to await the results of this trial and study before deciding whether to risk adjust for socioeconomic and demographic factors. We will monitor the results of the trial, studies, and recommendations. We are inviting public comment on how socioeconomic and demographic factors should be used in risk adjustment for the MSPB–PAC LTCH QRP measure.

(c) Measure Numerator and Denominator

The MPSB–PAC LTCH measure is a payment-standardized, risk-adjusted ratio that compares a given LTCH's Medicare spending against the Medicare spending of other LTCHs within a performance period. Similar to the hospital MSPB measure, the ratio allows for ease of comparison over time as it obviates the need to adjust for inflation or policy changes.

The MSPB–PAC LTCH QRP measure is calculated as the ratio of the MSPB–PAC Amount for each LTCH divided by the episode-weighted median MSPB–PAC Amount across all LTCHs. To calculate the MSPB–PAC Amount for each LTCH, one calculates the average of the ratio of the standardized spending for LTCH standard episodes over the expected spending (as predicted in risk adjustment) for LTCH standard episodes, and the average of the ratio of the standardized spending for LTCH site neutral episodes over the expected spending (as predicted in risk adjustment) for LTCH site neutral episodes. This quantity is then multiplied by the average episode spending level across all LTCHs nationally for standard and site neutral episodes. The denominator for an LTCH's MSPB–PAC LTCH QRP measure is the episode-weighted national median of the MSPB–PAC Amounts across all LTCHs. An MSPB–PAC LTCH QRP measure of less than 1 indicates that a given LTCH's Medicare spending is less than that of the national median LTCH during a performance period. Mathematically, this is represented in equation (A) below:

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[182] QualityNet, "CMS Price (Payment) Standardization—Detailed Methods" (Revised May 2015) *https://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228772057350.*

$$(A)\ MSPB\text{-}PAC\ LTCH\ Measure_j = \frac{MSPB\text{-}PAC\ Amount_j}{National\ Median\ MSPB\text{-}PAC\ Amount}$$

$$= \frac{\left(\frac{1}{n_j}\sum_{i\in\{I_j\}}\frac{Y_{ij}}{\widehat{Y_{ij}}}\right)\left(\frac{1}{n}\sum_j\sum_{i\in\{I_j\}}Y_{ij}\right)}{\begin{array}{c}Episode - Weighted\ Median\ of\\ LTCH\ Providers'MSPB\text{-}PAC\ Amount\end{array}}$$

where

- Y_{ij} = attributed standardized spending for episode *i* and provider *j*
- $\hat{Y}_{ij}$ = expected standardized spending for episode *i* and provider *j*, as predicted from risk adjustment
- n_j = number of episodes for provider *j*
- n = total number of episodes nationally
- $i \in \{I_j\}$ = all episodes *i* in the set of episodes attributed to provider *j*.

(3) Data Sources

The MSPB–PAC LTCH QRP resource use measure is an administrative claims-based measure. It uses Medicare Part A and Part B claims from FFS beneficiaries and Medicare eligibility files.

(4) Cohort

The measure cohort includes Medicare FFS beneficiaries with an LTCH treatment period ending during the data collection period.

(5) Reporting

If this proposed measure is finalized, we intend to provide initial confidential feedback to providers, prior to public reporting of this measure, based on Medicare FFS claims data from discharges in CY 2015 and CY 2016. We intend to publicly report this measure using claims data from discharges in CY 2016 and CY 2017.

We are proposing a minimum of 20 episodes for reporting and inclusion in the LTCH QRP. For the reliability calculation, as described in the measure specifications identified and for which a link has been provided above, we used two years of data (FY 2013 and FY 2014) to increase the statistical reliability of this measure. The reliability results support the 20 episode case minimum, and 98.83 percent of LTCHs had moderate or high reliability (above 0.4).

We are inviting public comment on our proposal to adopt the MSPB–PAC LTCH QRP measure for the LTCH QRP.

b. Proposal To Address the IMPACT Act Domain of Resource Use and Other Measures: Discharge to Community-Post Acute Care (PAC) Long-Term Care Hospital Quality Reporting Program

Sections 1899B(d)(1)(B) and 1899B(a)(2)(E)(ii) of the Act require the Secretary to specify a measure to address the domain of discharge to community by SNFs, LTCHs, and IRFs by October 1, 2016, and HHAs by January 1, 2017. We are proposing to adopt the measure, Discharge to Community-PAC LTCH QRP, for the LTCH QRP for the FY 2018 payment determination and subsequent years as a Medicare FFS claims-based measure to meet this requirement.

This proposed measure assesses successful discharge to the community from an LTCH setting, with successful discharge to the community including no unplanned rehospitalizations and no death in the 31 days following discharge from the LTCH. Specifically, this proposed measure reports an LTCH's risk-standardized rate of Medicare FFS patients who are discharged to the community following an LTCH stay, and do not have an unplanned readmission to an acute care hospital or LTCH in the 31 days following discharge to community, and who remain alive during the 31 days following discharge to community. The term "community," for this measure, is defined as home/self-care, with or without home health services, based on Patient Discharge Status Codes 01, 06, 81, and 86 on the Medicare FFS claim.[183] [184] This measure is conceptualized uniformly across the PAC settings, in terms of the definition of the discharge to community outcome, the approach to risk adjustment, and the measure calculation.

Discharge to a community setting is an important health care outcome for many patients for whom the overall goals of post-acute care include optimizing functional improvement, returning to a previous level of independence, and avoiding institutionalization. Returning to the community is also an important outcome for many patients who are not expected to make functional improvement during their LTCH stay, and for patients who may be expected to decline functionally due to their medical condition. The discharge to community outcome offers a multi-dimensional view of preparation for community life, including the cognitive, physical, and psychosocial elements involved in a discharge to the community.[185] [186]

In addition to being an important outcome from a patient and family perspective, patients discharged to community settings, on average, incur lower costs over the recovery episode, compared with those discharged to institutional settings.[187] [188] Given the high costs of care in institutional settings, encouraging LTCHs to prepare patients for discharge to community, when clinically appropriate, may have cost-saving implications for the Medicare program.[189] Also, providers have discovered that successful discharge to community was a major driver of their ability to achieve savings, where capitated payments for post-acute care were in place.[190] For patients who require long-term care due to persistent disability, discharge to community could result in lower long-term care costs for Medicaid and for patients' out-of-pocket expenditures.[191]

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[183] Further description of patient discharge status codes can be found, for example, at the following Web page: *https://med.noridianmedicare.com/web/jea/topics/claim-submission/patient-status-codes.*

[184] This definition is not intended to suggest that board and care homes, assisted living facilities, or other settings included in the definition of "community" for the purpose of this measure are the most integrated setting for any particular individual or group of individuals under the Americans with Disabilities Act (ADA) and Section 504.

[185] El-Solh AA, Saltzman SK, Ramadan FH, Naughton BJ. Validity of an artificial neural network in predicting discharge destination from a postacute geriatric rehabilitation unit. *Archives of physical medicine and rehabilitation.* 2000;81(10):1388–1393.

[186] Tanwir S, Montgomery K, Chari V, Nesathurai S. Stroke rehabilitation: availability of a family member as caregiver and discharge destination. *European journal of physical and rehabilitation medicine.* 2014;50(3):355–362.

[187] Dobrez D, Heinemann AW, Deutsch A, Manheim L, Mallinson T. Impact of Medicare's prospective payment system for inpatient rehabilitation facilities on stroke patient outcomes. *American journal of physical medicine & rehabilitation/Association of Academic Physiatrists.* 2010;89(3):198–204.

[188] Gage B, Morley M, Spain P, Ingber M. *Examining Post Acute Care Relationships in an Integrated Hospital System. Final Report.* RTI International;2009.

[189] *Ibid.*

[190] Doran JP, Zabinski SJ. Bundled payment initiatives for Medicare and non-Medicare total joint arthroplasty patients at a community hospital: bundles in the real world. *The journal of arthroplasty.* 2015;30(3):353–355.

Analyses conducted for ASPE on PAC episodes, using a 5 percent sample of 2006 Medicare claims, revealed that relatively high average, unadjusted Medicare payments are associated with discharge to institutional settings from IRFs, SNFs, LTCHs or HHAs, as compared with payments associated with discharge to community settings.[192] Average, unadjusted Medicare payments associated with discharge to community settings ranged from $0 to $4,017 for IRF discharges, $0 to $3,544 for SNF discharges, $0 to $4,706 for LTCH discharges, and $0 to $992 for HHA discharges. In contrast, payments associated with discharge to non-community settings were considerably higher, ranging from $11,847 to $25,364 for IRF discharges, $9,305 to $29,118 for SNF discharges, $12,465 to $18,205 for LTCH discharges, and $7,981 to $35,192 for HHA discharges.[193]

Measuring and comparing facility-level discharge to community rates is expected to help differentiate among facilities with varying performance in this important domain, and to help avoid disparities in care across patient groups. Variation in discharge to community rates has been reported within and across post-acute settings; across a variety of facility-level characteristics, such as geographic location (for example, regional location, urban or rural location), ownership (for example, for-profit or nonprofit), and freestanding or hospital-based units; and across patient-level characteristics, such as race and gender.[194] [195] [196] [197] [198] [199] Discharge to community rates in the IRF setting have been reported to range from about 60 to 80 percent.[200] [201] [202] [203] [204] [205] Longer-term studies show that rates of discharge to community from IRFs have decreased over time as IRF length of stay has decreased.[206] [207] Greater variation in discharge to community rates is seen in the SNF setting, with rates ranging from 31 to 65 percent.[208] [209] [210] [211] A multi-center study of 23 LTCHs demonstrated that 28.8 percent of 1,061 patients who were ventilator-dependent on admission were discharged to home.[212] A single-center study revealed that 31 percent of LTCH hemodialysis patients were discharged to home.[213] In the LTCH Medicare FFS population, using CY 2012–2013 national data, we found that approximately 25 percent of patients were discharged to the community. One study noted that 64 percent of beneficiaries who were discharged from the home health episode did not use any other acute or post-acute services paid by Medicare in the 30 days after discharge.[214] However, significant numbers of patients were admitted to hospitals (29 percent) and lesser numbers to SNFs (7.6 percent), IRFs (1.5 percent), home health (7.2 percent) or hospice (3.3 percent).[215]

Discharge to community is an actionable health care outcome, as targeted interventions have been shown to successfully increase discharge to community rates in a variety of post-acute settings.[216] [217] [218] [219] Many of these interventions involve discharge planning or specific rehabilitation strategies, such as addressing discharge barriers and improving medical and functional status.[220] [221] [222] [223] The effectiveness of these interventions suggests that improvement in discharge to community rates among post-acute care patients is possible through modifying provider-led processes and interventions.

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[191] Newcomer RJ, Ko M, Kang T, Harrington C, Hulett D, Bindman AB. Health Care Expenditures After Initiating Long-term Services and Supports in the Community Versus in a Nursing Facility. *Medical Care.* 2016;54(3):221–228.

[192] Gage B, Morley M, Spain P, Ingber M. *Examining Post Acute Care Relationships in an Integrated Hospital System. Final Report.* RTI International;2009.

[193] *Ibid.*

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[195] El-Solh AA, Saltzman SK, Ramadan FH, Naughton BJ. Validity of an artificial neural network in predicting discharge destination from a postacute geriatric rehabilitation unit. *Archives of physical medicine and rehabilitation.* 2000;81(10):1388–1393.

[196] *March 2015 Report to the Congress: Medicare Payment Policy.* Medicare Payment Advisory Commission;2015.

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[205] Kushner DS, Peters KM, Johnson-Greene D. Evaluating Siebens Domain Management Model for Inpatient Rehabilitation to Increase Functional Independence and Discharge Rate to Home in Geriatric Patients. *Archives of physical medicine and rehabilitation.* 2015;96(7):1310–1318.

[206] Galloway RV, Granger CV, Karmarkar AM, et al. The Uniform Data System for Medical Rehabilitation: report of patients with debility discharged from inpatient rehabilitation programs in 2000–2010. *American journal of physical medicine & rehabilitation/Association of Academic Physiatrists.* 2013;92(1):14–27.

[207] Mallinson T, Deutsch A, Bateman J, et al. Comparison of discharge functional status after rehabilitation in skilled nursing, home health, and medical rehabilitation settings for patients after hip fracture repair. *Archives of physical medicine and rehabilitation.* 2014;95(2):209–217.

[208] El-Solh AA, Saltzman SK, Ramadan FH, Naughton BJ. Validity of an artificial neural network in predicting discharge destination from a postacute geriatric rehabilitation unit. *Archives of physical medicine and rehabilitation.* 2000;81(10):1388–1393.

[209] Hall RK, Toles M, Massing M, et al. Utilization of acute care among patients with ESRD discharged home from skilled nursing facilities. *Clinical journal of the American Society of Nephrology: CJASN.* 2015;10(3):428–434.

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[215] *Ibid.*

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[218] Berkowitz RE, Jones RN, Rieder R, et al. Improving disposition outcomes for patients in a geriatric skilled nursing facility. *Journal of the American Geriatrics Society.* 2011;59(6):1130–1136.

[219] Kushner DS, Peters KM, Johnson-Greene D. Evaluating use of the Siebens Domain Management Model during inpatient rehabilitation to increase functional independence and discharge rate to home in stroke patients. *PM & R: the journal of injury, function, and rehabilitation.* 2015;7(4):354–364.

A TEP convened by our measure development contractor was strongly supportive of the importance of measuring discharge to community outcomes, and implementing the proposed measure, Discharge to Community-PAC LTCH QRP in the LTCH QRP. The panel provided input on the technical specifications of this proposed measure, including the feasibility of implementing the measure, as well as the overall measure reliability and validity. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 9, 2015, through December 8, 2015. Several stakeholders and organizations, including the MedPAC, among others, supported this measure for implementation. The public comment summary report for the proposed measure is available on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The NQF-convened MAP met on December 14 and 15, 2015, and provided input on the use of this proposed Discharge to Community-PAC LTCH QRP measure in the LTCH QRP. The MAP encouraged continued development of the proposed measure to meet the mandate of the IMPACT Act. The MAP supported the alignment of this proposed measure across PAC settings, using standardized claims data. More information about the MAP's recommendations for this measure is available at: *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.*

Since the MAP's review and recommendation of continued development, we have continued to refine risk-adjustment models and conduct measure testing for this measure, as recommended by the MAP. This proposed measure is consistent with the information submitted to the MAP and is scientifically acceptable for current specification in the LTCH QRP. As discussed with the MAP, we fully anticipate that additional analyses will continue as we submit this measure to the ongoing measure maintenance process.

We reviewed the NQF's consensus-endorsed measures and were unable to identify any NQF-endorsed resource use or other measures for post-acute care focused on discharge to community. In addition, we are unaware of any other post-acute care measures for discharge to community that have been endorsed or adopted by other consensus organizations. Therefore, we are proposing the measure, Discharge to Community-PAC LTCH QRP, under the Secretary's authority to specify non-NQF-endorsed measures under section 1899B(e)(2)(B) of the Act.

We are proposing to use data from the Medicare FFS claims and Medicare eligibility files to calculate this proposed measure. We are proposing to use data from the "Patient Discharge Status Code" on Medicare FFS claims to determine whether a patient was discharged to a community setting for calculation of this proposed measure. In all PAC settings, we tested the accuracy of determining discharge to a community setting using the "Patient Discharge Status Code" on the PAC claim by examining whether discharge to community coding based on PAC claim data agreed with discharge to community coding based on PAC assessment data. We found excellent agreement between the two data sources in all PAC settings, ranging from 94.6 percent to 98.8 percent. Specifically, in the LTCH setting, using 2013 data, we found 95.6 percent agreement in coding of community and non-community discharges when comparing discharge status codes on claims and the Discharge Location (item A2100) codes on the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set Version 1.01. We further examined the accuracy of the "Patient Discharge Status Code" on the PAC claim by assessing how frequently discharges to an acute care hospital were confirmed by follow-up acute care claims. We discovered that 88 percent to 91 percent of IRF, LTCH, and SNF claims with acute care discharge status codes were followed by an acute care claim on the day of, or day after, PAC discharge. We believe these data support the use of the claims "Patient Discharge Status Code" for determining discharge to a community setting for this measure. In addition, this measure can feasibly be implemented in the LTCH QRP because all data used for measure calculation are derived from Medicare FFS claims and eligibility files, which are already available to CMS.

Based on the evidence discussed above, we are proposing to adopt the measure, Discharge to Community-PAC LTCH QRP, for the LTCH QRP for FY 2018 payment determination and subsequent years. This proposed measure is calculated using 2 years of data. We are proposing a minimum of 25 eligible stays in a given LTCH for public reporting of the proposed measure for that LTCH. Since Medicare FFS claims data are already reported to the Medicare program for payment purposes, and Medicare eligibility files are also available, LTCHs will not be required to report any additional data to CMS for calculation of this measure. The proposed measure denominator is the risk-adjusted expected number of discharges to community. The proposed measure numerator is the risk-adjusted estimate of the number of patients who are discharged to the community, do not have an unplanned readmission to an acute care hospital or LTCH in the 31-day post-discharge observation window, and who remain alive during the post-discharge observation window. The measure is risk-adjusted for variables such as age and sex, principal diagnosis, comorbidities, ventilator status, ESRD status, and dialysis, among other variables. For technical information about this proposed measure, including information about the measure calculation, risk adjustment, and denominator exclusions, we refer readers to the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 LTCH QRP NPRM, available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-*

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Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html.

If this proposed measure is finalized, we intend to provide initial confidential feedback to LTCHs, prior to public reporting of this measure, based on Medicare FFS claims data from discharges in CY 2015 and 2016. We intend to publicly report this measure using claims data from discharges in CY 2016 and 2017. We plan to submit this proposed measure to the NQF for consideration for endorsement.

We are inviting public comment on our proposal to adopt the measure, Discharge to Community-PAC LTCH QRP, for the LTCH QRP.

c. Proposal To Address the IMPACT Act Domain of Resource Use and Other Measures: Potentially Preventable 30-Day Post-Discharge Readmission Measure for Long-Term Care Hospital Quality Reporting Program

Sections 1899B(a)(2)(E)(ii) and 1899B(d)(1)(C) of the Act require the Secretary to specify measures to address the domain of all-condition risk-adjusted potentially preventable hospital readmission rates by SNFs, LTCHs, and IRFs by October 1, 2016, and HHAs by January 1, 2017. We are proposing the measure Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP as a Medicare FFS claims-based measure to meet this requirement for the FY 2018 payment determination and subsequent years.

The proposed measure assesses the facility-level risk-standardized rate of unplanned, potentially preventable hospital readmissions for Medicare FFS beneficiaries in the 30 days post-LTCH discharge. The LTCH admission must have occurred within up to 30 days of discharge from a prior proximal hospital stay which is defined as an inpatient admission to an acute care hospital (including IPPS, CAH, or a psychiatric hospital). Hospital readmissions include readmissions to a short-stay acute care hospital or an LTCH, with a diagnosis considered to be unplanned and potentially preventable. This proposed measure is claims-based, requiring no additional data collection or submission burden for LTCHs. Because the measure denominator is based on LTCH admissions, each Medicare beneficiary may be included in the measure multiple times within the measurement period. Readmissions counted in this measure are identified by examining Medicare FFS claims data for readmissions to either acute care hospitals (IPPS or CAH) or LTCHs that occur during a 30-day window beginning two days after LTCH discharge. This measure is conceptualized uniformly across the PAC settings, in terms of the measure definition, the approach to risk adjustment, and the measure calculation. Our approach for defining potentially preventable hospital readmissions is described in more detail below.

Hospital readmissions among the Medicare population, including beneficiaries that utilize PAC, are common, costly, and often preventable.[224] [225] MedPAC and a study by Jencks et al. estimated that 17 to 20 percent of Medicare beneficiaries discharged from the hospital were readmitted within 30 days. MedPAC found that more than 75 percent of 30-day and 15-day readmissions and 84 percent of 7-day readmissions were considered "potentially preventable." [226] In addition, MedPAC calculated that annual Medicare spending on potentially preventable readmissions would be $12 billion for 30-day, $8 billion for 15-day, and $5 billion for 7-day readmissions.[227] For hospital readmissions from one post-acute care setting, SNFs, MedPAC deemed 76 percent of readmissions as "potentially avoidable"—associated with $12 billion in Medicare expenditures.[228] Mor et al. analyzed 2006 Medicare claims and SNF assessment data (Minimum Data Set), and reported a 23.5 percent readmission rate from SNFs, associated with $4.3B in expenditures.[229] Fewer studies have investigated potentially preventable readmission rates from the remaining post-acute care settings.

We have addressed the high rates of hospital readmissions in the acute care setting as well as in PAC. For example, we developed the following measure: All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512), as well as similar measures for other PAC providers (NQF #2502 for IRFs and NQF #2510 for SNFs).[230] These measures are endorsed by the NQF, and the NQF-endorsed LTCH measure (NQF #2512) was adopted into the LTCH QRP in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49730 through 49731). Note that these NQF-endorsed measures assess all-cause unplanned readmissions.

Several general methods and algorithms have been developed to assess potentially avoidable or preventable hospitalizations and readmissions for the Medicare population. These include the Agency for Healthcare Research and Quality's (AHRQ's) Prevention Quality Indicators, approaches developed by MedPAC, and proprietary approaches, such as the 3M™ algorithm for Potentially Preventable Readmissions.[231] [232] [233] Recent work led by Kramer et al. for MedPAC identified 13 conditions for which readmissions were deemed as potentially preventable among SNF and IRF populations.[234] [235] Although much of the existing literature addresses hospital readmissions more broadly and potentially avoidable hospitalizations for specific settings like long-term care, these findings are relevant to the development of potentially preventable readmission measures for PAC.[236] [237] [238]

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Continued

Potentially Preventable Readmission Measure Definition: We conducted a comprehensive environmental scan, analyzed claims data, and obtained input from a TEP to develop a definition and list of conditions for which hospital readmissions are potentially preventable. The Ambulatory Care Sensitive Conditions and Prevention Quality Indicators, developed by AHRQ, served as the starting point in this work. For patients in the 30-day post-PAC discharge period, a potentially preventable readmission (PPR) refers to a readmission for which the probability of occurrence could be minimized with adequately planned, explained, and implemented post-discharge instructions, including the establishment of appropriate follow-up ambulatory care. Our list of PPR conditions is categorized by 3 clinical rationale groupings:

- Inadequate management of chronic conditions;
- Inadequate management of infections; and
- Inadequate management of other unplanned events.

Additional details regarding the definition for potentially preventable readmissions are available in the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 LTCH QRP NPRM, available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html.*

This proposed measure focuses on readmissions that are potentially preventable and also unplanned. Similar to the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512), this proposed measure uses the current version of the CMS Planned Readmission Algorithm as the main component for identifying planned readmissions. A complete description of the CMS Planned Readmission Algorithm, which includes lists of planned diagnoses and procedures, can be found on the CMS Web site at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.* In addition to the CMS Planned Readmission Algorithm, this proposed measure incorporates procedures that are considered planned in post-acute care settings, as identified in consultation with TEPs. Full details on the planned readmissions criteria used, including the CMS Planned Readmission Algorithm and additional procedures considered planned for post-acute care, can be found in the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 LTCH QRP NPRM, available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html.*

The proposed measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP, assesses potentially preventable readmission rates while accounting for patient demographics, principal diagnosis in the prior hospital stay, comorbidities, and other patient factors. While estimating the predictive power of patient characteristics, the model also estimates a facility-specific effect, common to patients treated in each facility. This proposed measure is calculated for each LTCH based on the ratio of the predicted number of risk-adjusted, unplanned, potentially preventable hospital readmissions that occur within 30 days after an LTCH discharge, including the estimated facility effect, to the estimated predicted number of risk-adjusted, unplanned inpatient hospital readmissions for the same patients treated at the average LTCH. A ratio above 1.0 indicates a higher than expected readmission rate (worse) while a ratio below 1.0 indicates a lower than expected readmission rate (better). This ratio is referred to as the standardized risk ratio (SRR). The SRR is then multiplied by the overall national raw rate of potentially preventable readmissions for all LTCH stays. The resulting rate is the risk-standardized readmission rate (RSRR) of potentially preventable readmissions.

An eligible LTCH stay is followed until: (1) The 30-day post-discharge period ends; or (2) the patient is readmitted to an acute care hospital (IPPS or CAH) or LTCH. If the readmission is unplanned and potentially preventable, it is counted as a readmission in the measure calculation. If the readmission is planned, the readmission is not counted in the measure rate.

This measure is risk adjusted. The risk adjustment modeling estimates the effects of patient characteristics, comorbidities, and select health care variables on the probability of readmission. More specifically, the risk-adjustment model for LTCHs account for demographic characteristics (age, sex, original reason for Medicare entitlement), principal diagnosis during the prior proximal hospital stay, body system specific surgical indicators, prolonged mechanical ventilation indicator, comorbidities, length of stay during the patient's prior proximal hospital stay, length of stay in the intensive care and coronary care unit (ICU and CCU), and number of acute care hospitalizations in the preceding 365 days.

The proposed measure is calculated using 2 consecutive calendar years of FFS claims data, to ensure the statistical reliability of this measure for facilities. In addition, we are proposing a minimum of 25 eligible stays for public reporting of the proposed measure.

A TEP convened by our measure contractor provided recommendations on the technical specifications of this proposed measure, including the development of an approach to define potentially preventable hospital readmission for PAC. Details from the TEP meetings, including TEP members' ratings of conditions proposed as being potentially preventable, are available in the TEP summary report available on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.* We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 2 through December 1, 2015. Comments on the measure varied, with some commenters supportive of the proposed measure, while others either were not in favor of the measure, or suggested potential modifications to the measure specifications, such as including standardized function data. A summary of the public comments is also available on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

The MAP encouraged continued development of the proposed measure. Specifically, the MAP stressed the need to promote shared accountability and ensure effective care transitions. More information about the MAP's recommendations for this measure is available at: *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC–*

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LTC.aspx. At the time, the risk-adjustment model was still under development. Following completion of that development work, we were able to test for measure validity and reliability as identified in the measure specifications document provided above. Testing results are within range for similar outcome measures finalized in public reporting and value-based purchasing programs, including the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512) adopted into the LTCH QRP.

We reviewed the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed measures focused on potentially preventable hospital readmissions. We are unaware of any other measures for this IMPACT Act domain that have been endorsed or adopted by other consensus organizations. Therefore, we are proposing the Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP, under the Secretary's authority to specify non-NQF-endorsed measures under section 1899B(e)(2)(B) of the Act, for the LTCH QRP for the FY 2018 payment determination and subsequent years, given the evidence previously discussed above.

We plan to submit the proposed measure to the NQF for consideration of endorsement. If this proposed measure is finalized, we intend to provide initial confidential feedback to LTCHs, prior to public reporting of this proposed measure, based on 2 calendar years of data from discharges in CY 2015 and 2016. We intend to publicly report this proposed measure using data from CY 2016 and 2017.

We are inviting public comment on our proposal to adopt the measure, Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP.

7. LTCH QRP Quality Measure Proposed for the FY 2020 Payment Determination and Subsequent Years

a. Background

In addition to the measures we are retaining as described in section VIII.C.5. of the preamble of this proposed rule under our policy described in section VIII.C.3. of the preamble of this proposed rule and the new quality measures proposed in section VIII.C.6. of the preamble of this proposed rule for the FY 2018 payment determinations and subsequent years, we are also proposing one new quality measure to meet the requirements of the IMPACT Act for the FY 2020 payment determination and subsequent years. The proposed measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-Post-Acute Care (PAC) LTCH QRP, addresses the IMPACT Act quality domain of Medication Reconciliation.

b. Quality Measure Addressing the IMPACT Act Domain of Medication Reconciliation: Drug Regimen Review Conducted With Follow-up for Identified Issues-Post Acute Care LTCH QRP

Sections 1899B(a)(2)(E)(i)(III) and 1899B(c)(1)(C) of the Act require the Secretary to specify a quality measure to address the domain of medication reconciliation by October 1, 2018 for IRFs, LTCHs, and SNFs, and by January 1, 2017 for HHAs. We are proposing to adopt the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, for the LTCH QRP as a patient-assessment based, cross-setting quality measure to meet the IMPACT Act requirements with data collection beginning April 1, 2018 for the FY 2020 payment determinations and subsequent years.

This proposed measure assesses whether PAC providers were responsive to potential or actual clinically significant medication issue(s) when such issues were identified. Specifically, the proposed quality measure reports the percentage of patient stays in which a drug regimen review was conducted at the time of admission and timely follow-up with a physician occurred each time potential clinically significant medication issues were identified throughout that stay.

For this proposed quality measure, drug regimen review is defined as the review of all medications or drugs the patient is taking to identify any potentially clinically significant medication issues. This proposed quality measure utilizes both the processes of medication reconciliation and a drug regimen review, in the event an actual or potential medication issue occurred. The proposed measure informs whether the PAC facility identified and addressed each clinically significant medication issue and if the facility responded or addressed the medication issue in a timely manner. Of note, drug regimen review in PAC settings is generally considered to include medication reconciliation and review of the patient's drug regimen to identify potential clinically significant medication issues.[239] This measure is applied uniformly across the PAC settings.

Medication reconciliation is a process of reviewing an individual's complete and current medication list. Medication reconciliation is a recognized process for reducing the occurrence of medication discrepancies that may lead to Adverse Drug Events (ADEs).[240] Medication discrepancies occur when there is conflicting information documented in the medical records. The World Health Organization regards medication reconciliation as a standard operating protocol necessary to reduce the potential for ADEs that cause harm to patients. Medication reconciliation is an important patient safety process that addresses medication accuracy during transitions in patient care and in identifying preventable ADEs.[241] The Joint Commission added medication reconciliation to its list of National Patient Safety Goals (2005), suggesting that medication reconciliation is an integral component of medication safety.[242] The Society of Hospital Medicine published a statement in agreement of the Joint Commission's emphasis and value of medication reconciliation as a patient safety goal.[243] There is universal agreement that medication reconciliation directly addresses patient safety issues that can result from medication miscommunication and unavailable or incorrect information.[244] [245] [246]

The performance of timely medication reconciliation is valuable to the process of drug regimen review. Preventing and responding to ADEs is of critical importance as ADEs account for significant increases in health services utilization and costs,[247] [248] [249] including subsequent emergency room visits and re-hospitalizations.[250] Annual health care costs in the United States are estimated at $3.5 billion, resulting in 7,000 deaths annually.[251] [252]

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[239] Institute of Medicine. Preventing Medication Errors. Washington DC: National Academies Press; 2006.

[240] *Ibid*

[241] Leotsakos A., et al. Standardization in patient safety: the WHO High 5s project. Int J Qual Health Care. 2014:26(2):109–116.

[242] The Joint Commission. 2016 Long Term Care: National Patient Safety Goals Medicare/Medicaid Certification-based Option. (NPSG.03.06.01).

[243] Greenwald, J. L., Halasyamani, L., Greene, J., LaCivita, C., et al. (2010). Making inpatient medication reconciliation patient centered, clinically relevant and implementable: a consensus statement on key principles and necessary first steps. Journal of Hospital Medicine, 5(8), 477–485.

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[246] IHI. Medication Reconciliation to Prevent Adverse Drug Events [Internet]. Cambridge, MA: Institute for Healthcare Improvement; [cited 2016 Jan 11]. Available from: *http://www.ihi.org/topics/adesmedicationreconciliation/Pages/default.aspx*.

Medication errors include the duplication of medications, delivery of an incorrect drug, inappropriate drug omissions, or errors in the dosage, route, frequency, and duration of medications. Medication errors are one of the most common types of medical error and can occur at any point in the process of ordering and delivering a medication. Medication errors have the potential to result in an ADE.[253] [254] [255] [256] [257] [258] Inappropriately prescribed medications are also considered a major healthcare concern in the United States for the elderly population, with costs of roughly $7.2 billion annually.[259]

There is strong evidence that medication discrepancies occur during transfers from acute care facilities to post-acute care facilities. Discrepancies occur when there is conflicting information documented in the medical records. Almost one-third of medication discrepancies have the potential to cause patient harm.[260] An estimated 50 percent of patients experienced a clinically important medication error after hospital discharge in an analysis of two tertiary care academic hospitals.[261]

Medication reconciliation has been identified as an area for improvement during transfer from the acute care facility to the receiving post-acute care facility. PAC facilities report gaps in medication information between the acute care hospital and the receiving post-acute care setting when performing medication reconciliation.[262] [263] Hospital discharge has been identified as a particularly high risk time point, with evidence that medication reconciliation identifies high levels of discrepancy.[264] [265] [266] [267] [268] [269] Also, there is evidence that medication reconciliation discrepancies occur throughout the patient stay.[270] [271] For older patients, who may have multiple comorbid conditions and thus multiple medications, transitions between acute and post-acute care settings can be further complicated,[272] and medication reconciliation and patient knowledge (medication literacy) can be inadequate post-discharge.[273] The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, provides an important component of care coordination for PAC settings and would affect a large proportion of the Medicare population who transfer from hospitals into PAC services each year. For example, in 2013, 1.7 million Medicare FFS beneficiaries had SNF stays, 338,000 beneficiaries had IRF stays, and 122,000 beneficiaries had LTCH stays.[274]

A TEP convened by our measure development contractor provided input on the technical specifications of this proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, including components of reliability, validity and the feasibility of implementing the measure across PAC settings. The TEP supported the measure's implementation across PAC settings and was supportive of our plans to standardize this measure for cross-setting development. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We solicited stakeholder feedback on the development of this measure by means of a public comment period held from September 18 through October 6, 2015. Through public comments submitted by several stakeholders and organizations, we received support for implementation of this proposed measure. The public comment summary report for the proposed measure is available on the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

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The NQF-convened MAP met on December 14 and 15, 2015 and provided input on the use of this proposed measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP. The MAP encouraged continued development of the proposed quality measure to meet the mandate added by the IMPACT Act. The MAP agreed with the measure gaps identified by CMS including medication reconciliation, and stressed that medication reconciliation be present as an ongoing process. More information about the MAP's recommendations for this measure is available at: *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC–LTC.aspx.*

Since the MAP's review and recommendation of continued development, we have continued to refine this proposed measure in compliance with the MAP's recommendations. The proposed measure is both consistent with the information submitted to the MAP and support its scientific acceptability for use in quality reporting programs. Therefore, we are proposing this measure for implementation in the LTCH QRP as required by the IMPACT Act.

We reviewed the NQF's endorsed measures and identified one NQF-endorsed cross-setting and quality measure related to medication reconciliation, which applies to the SNF, LTCH, IRF, and HHA settings of care: Care for Older Adults (COA), (NQF #0553). The quality measure, Care for Older Adults (COA), (NQF #0553) assesses the percentage of adults 66 years and older who had a medication review. The Care for Older Adults (COA), (NQF #0553) measure requires at least one medication review conducted by a prescribing practitioner or clinical pharmacist during the measurement year and the presence of a medication list in the medical record. This is in contrast to the proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, which reports the percentage of patient stays in which a drug regimen review was conducted at the time of admission and that timely follow-up with a physician occurred each time one or more potential clinically significant medication issues were identified throughout that stay.

After careful review of both quality measures, we have decided to propose the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP for the following reasons:

- The IMPACT Act requires the implementation of quality measures, using patient assessment data that are standardized and interoperable across PAC settings. The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, employs three standardized patient-assessment data elements for each of the four PAC settings so that data are standardized, interoperable, and comparable; whereas, the Care for Older Adults (COA), (NQF #0553) quality measure does not contain data elements that are standardized across all four PAC settings.
- The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, requires the identification of potential clinically significant medication issues at the beginning, during, and at the end of the patient's stay to capture data on each patient's complete PAC stay; whereas, the Care for Older Adults (COA), (NQF #0553) quality measure only requires annual documentation in the form of a medication list in the medical record of the target population.
- The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, includes identification of the potential clinically significant medication issues and communication with the physician (or physician designee) as well as resolution of the issue(s) within a rapid timeframe (by midnight of the next calendar day); whereas, the Care for Older Adults (COA), (NQF #0553) quality measure does not include any follow-up or timeframe in which the follow-up would need to occur.
- The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, does not have age exclusions; whereas, the Care for Older Adults (COA), (NQF #0553) quality measure limits the measure's population to patients aged 66 and older.
- The proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, would be reported to LTCHs quarterly to facilitate internal quality monitoring and quality improvement in areas such as patient safety, care coordination, and patient satisfaction; whereas the Care for Older Adults (COA), (NQF #0553) quality measure would not enable quarterly quality updates, and thus data comparisons within and across PAC providers would be difficult due to the limited data and scope of the data collected.

Therefore, based on the evidence discussed above, we are proposing to adopt the quality measure entitled, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, for the LTCH QRP for FY 2020 payment determination and subsequent years. We plan to submit the quality measure to the NQF for consideration for endorsement.

The calculation of the proposed quality measure would be based on the data collection of three standardized items to be included in the LTCH CARE Data Set. The collection of data by means of the standardized items would be obtained at admission and discharge. For more information about the data submission required for this proposed measure, we refer readers to section VIII.C.9. of the preamble of this proposed rule.

The standardized items used to calculate this proposed quality measure do not duplicate existing items currently used for data collection within the LTCH CARE Data Set. The proposed measure denominator is the number of patient stays with a discharge or expired assessment during the reporting period. The proposed measure numerator is the number of stays in the denominator where the medical record contains documentation of a drug regimen review conducted at: (1) Admission; and (2) discharge with a lookback through the entire patient stay with all potential clinically significant medication issues identified during the course of care and followed up with a physician or physician designee by midnight of the next calendar day. This measure is not risk adjusted. For technical information about this proposed measure, including information about the measure calculation and discussion pertaining to the standardized items used to calculate this measure, we refer readers to the document titled, Proposed Measure Specifications for Measures Proposed in the FY 2017 LTCH QRP NPRM available at: *http://www.cms.gov/Medicare/Quality-Initiative-Patient-Assessment-Instruments/LTCH-Quality-Reporting-Program-Measures-Information-.html.*

Data for the proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, would be collected using the Long-Term Care Hospital LTCH CARE Data Set with submission through the Quality Improvement Evaluation System (QIES) Assessment Submission and Processing (ASAP) system.

We are inviting public comment on our proposal to adopt the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP for the LTCH QRP.

8. LTCH QRP Quality Measures and Measure Concepts Under Consideration for Future Years

We are inviting comment on the importance, relevance, appropriateness, and applicability of each of the quality measures listed in the table below for future years in the LTCH QRP. We are developing a measure related to the IMPACT Act domain, "Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual, when the individual transitions." We are considering the possibility of adding quality measures that rely on the patient's perspective; that is, measures that include patient-reported experience of care and health status data. We recently posted a "Request for Information to Aid in the Design and Development of a Survey Regarding Patient and Family Member Experiences with Care Received in Long-Term Care Hospitals" (80 FR 72722 through 72725).

Also, we are considering a measure focused on pain that relies on the collection of patient-reported pain data, and another that documents whether a patient has an Advance Care Plan. Finally, we are considering measures related to patient safety: Venous Thromboembolism Prophylaxis, Ventilator Weaning (Liberation) Rate, Compliance with Spontaneous Breathing Trial (SBT) (including Tracheostomy Collar Trial (TCT) or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of the LTCH Stay, and Patients Who Received an Antipsychotic Medication.

LTCH QRP Quality Measures Under Consideration for Future Years

IMPACT Act Domain: Accurately communicating the existence of and providing for the transfer of health information and care preferences of an individual to the individual, family caregiver of the individual, and providers of services furnishing items and services to the individual, when the individual transitions

IMPACT Act Measure

Transfer of health information and care preferences when an individual transitions

NQS Priority: Patient- and Caregiver-Centered Care

Measures

- Patient Experience of Care
- Percent of Patients with Moderate to Severe Pain
- Advance Care Plan

NQS Priority: Patient Safety

Measures

- Ventilator Weaning (Liberation) Rate
- Compliance with Spontaneous Breathing Trial (SBT) (including Tracheostomy Collar Trial (TCT) or Continuous Positive Airway Pressure (CPAP) Breathing Trial) by Day 2 of the LTCH Stay
- Patients Who Received an Antipsychotic Medication
- Venous Thromboembolism Prophylaxis

9. Proposed Form, Manner, and Timing of Quality Data Submission for the FY 2018 Payment Determination and Subsequent Years

a. Background

Section 1886(m)(5)(C) of the Act requires that, for the FY 2014 payment determination and subsequent years, each LTCH submit to the Secretary data on quality measures specified by the Secretary. In addition, section 1886(m)(5)(F) of the Act requires that, for the fiscal year beginning on the specified application date, as defined in section 1899B(a)(2)(E) of the Act, and each subsequent year, each LTCH submit to the Secretary data on measures specified by the Secretary under section 1899B of the Act. The data required under sections 1886(m)(5)(C) and (F) of the Act must be submitted in a form and manner, and at a time, specified by the Secretary. As required by section 1886(m)(5)(A)(i) of the Act, for any LTCH that does not submit data in accordance with sections 1886(m)(5)(C) and (F) of the Act for a given fiscal year, the annual payment for discharges occurring during the fiscal year must be reduced by 2 percentage points.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49749 through 49752), we:

- Adopted timing for new LTCHs to begin reporting quality data under the LTCH QRP for the FY 2017 payment determination and subsequent years; and
- Adopted new deadlines that allow 4.5 months (approximately 135 days) after the end of each calendar year quarter for quality data submission, beginning with quarter 4 of 2015 (October 2015 through December 2015). The new deadlines apply to all LTCH QRP quality measures (except Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431)) for the FY 2017 and FY 2018 payment determinations and subsequent years.

b. Timeline for Data Submission Under the LTCH QRP for the FY 2018 Payment Determination and Subsequent Years

The table below presents the data collection period, data submission (for the LTCH CARE Data Set-assessment based and CDC measures) and data correction timelines for quality measures affecting the FY 2018 and subsequent years payment determination.

Summary Details on the LTCH CARE Data Set and CDC NHSN Data Collection Period and Data Submission Timeline for Previously Adopted Quality Measures Affecting the FY 2018 Payment Determination and Subsequent Years *

Quality measure	Submission method	Data collection/submission quarterly reporting period(s)	Quarterly review and correction period and data submission deadlines for payment determination	First APU determination affected
NQF #0678: Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (76 FR 51748 through 51750).	LTCH CARE Data Set/QIES ASAP.	1/1/16–3/31/16, 4/1/16–6/30/16, 7/1/16–9/30/16, 10/01/16–12/31/16; Quarterly for each subsequent calendar year.	8/15/16 (Q1), 11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Approximately 135 days after the end of each quarter.	FY 2018.
NQF #0138: NHSN Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (76 FR 51745 through 51747).	CDC NHSN	1/1/16–3/31/16, 4/1/16–6/30/16, 7/1/16–9/30/16, 10/01/16–12/31/16; Quarterly for each subsequent calendar year.	8/15/16 (Q1), 11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Approximately 135 days after the end of each quarter.	FY 2018.
NQF #0139: NHSN Central-Line Associated Bloodstream Infection (CLABSI) Outcome Measure (76 FR 51747 through 51748).	CDC NHSN	1/1/16–3/31/16, 4/1/16–6/30/16, 7/1/16–9/30/16, 10/01/16–12/31/16; Quarterly for each subsequent calendar year.	8/15/16 (Q1), 11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Approximately 135 days after the end of each quarter.	FY 2018.
NQF #1716: NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (78 FR 50863 through 50865).	CDC NHSN	1/1/16–3/31/16, 4/1/16–6/30/16, 7/1/16–9/30/16, 10/01/16–12/31/16; Quarterly for each subsequent calendar year.	8/15/16 (Q1), 11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Approximately 135 days after the end of each quarter.	FY 2018.
NQF #1717: NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (78 FR 50865 through 50868).	CDC NHSN	1/1/16–3/31/16, 4/1/16–6/30/16, 7/1/16–9/30/16, 10/01/16–12/31/16; Quarterly for each subsequent calendar year.	8/15/16 (Q1), 11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Approximately 135 days after the end of each quarter.	FY 2018.
NHSN Ventilator-Associated Event (VAE) Outcome Measure (79 FR 50301 through 50305).	CDC NHSN	1/1/16–3/31/16, 4/1/16–6/30/16, 7/1/16–9/30/16, 10/01/16–12/31/16; Quarterly for each subsequent calendar year.	8/15/16 (Q1), 11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Approximately 135 days after the end of each quarter.	FY 2018.
NQF #0680: Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (77 FR 53624 through 53627).	LTCH CARE Data Set/QIES ASAP.	10/1/15–12/31/15, 1/1/16–3/31/16**.	5/15/16, 8/15/16**	FY 2018.
NQF #0431: Influenza Vaccination Coverage Among Healthcare Personnel (77 FR 53630 through 53631).	CDC NHSN	10/1/16–3/31/17, 10/1–3/31 for subsequent years.	5/15/17, 5/15 for subsequent years.	FY 2018.
NQF #2512: All-Cause Unplanned Readmission Measure for 30-Days Post-Discharge from Long-Term Care Hospitals (78 FR 50868 through 50874).	Medicare FFS Claims Data.	N/A	N/A	FY 2018.
NQF #0674: Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (80 FR 49736 through 49739).	LTCH CARE Data Set/QIES ASAP.	4/1/16–6/30/16, 7/1/16–9/30/16, 10/1/16–12/31/16; Quarterly for each subsequent calendar year.	11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Quarterly approximately 135 days after the end of each quarter for subsequent years.	FY 2018.
NQF #2631: Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (79 FR 50298 through 50301).	LTCH CARE Data Set/QIES ASAP.	4/1/16–6/30/16, 7/1/16–9/30/16, 10/1/16–12/31/16; Quarterly for each subsequent calendar year.	11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Quarterly approximately 135 days after the end of each quarter for subsequent years.	FY 2018.
NQF #2631: Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (80 FR 49739 through 49747).	LTCH CARE Data Set/QIES ASAP.	4/1/16–6/30/16, 7/1/16–9/30/16, 10/1/16–12/31/16; Quarterly for each subsequent calendar year.	11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Quarterly approximately 135 days after the end of each quarter for subsequent years.	FY 2018.

SUMMARY DETAILS ON THE LTCH CARE DATA SET AND CDC NHSN DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR PREVIOUSLY ADOPTED QUALITY MEASURES AFFECTING THE FY 2018 PAYMENT DETERMINATION AND SUBSEQUENT YEARS *—Continued

Quality measure	Submission method	Data collection/submission quarterly reporting period(s)	Quarterly review and correction period and data submission deadlines for payment determination	First APU determination affected
NQF #2632: Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital Patients Requiring Ventilator Support (79 FR 50298 through 50301).	LTCH CARE Data Set/QIES ASAP.	4/1/16–6/30/16, 7/1/16–9/30/16, 10/1/16–12/31/16; Quarterly for each subsequent calendar year.	11/15/16 (Q2), 2/15/17 (Q3), 5/15/17 (Q4); Quarterly approximately 135 days after the end of each quarter for subsequent years.	FY 2018.

* We refer readers to the table below for an illustration of the CY quarterly data collection/submission quarterly reporting periods and correction and submission deadlines for all APU years.

** For this measure, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine, we refer readers to the proposals on data submission for this measure we are making in section VIII.C.9.d. of the preamble of this proposed rule. These proposals for the FY 2019 payment determination and for FY 2020 payment determination and subsequent years are illustrated in the tables in that section.

Further, in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49749 through 49752), we established that the LTCH CARE Data Set-based and CDC NHSN measures finalized for adoption into the LTCH QRP would follow a calendar year schedule with quarterly reporting periods, followed by quarterly review and correction periods and submission deadlines. This pattern is illustrated in the table below and is in place for all APU years unless otherwise specified. We also wish to illustrate that for the measures finalized for use in the LTCH QRP that use the LTCH CARE Data Set or CDC NHSN data sources, payment determination would subsequently use the data collection and deadlines shown below unless otherwise specified.

ANNUAL CY LTCH CARE DATA SET AND CDC NHSN DATA COLLECTION/SUBMISSION REPORTING PERIODS AND DATA SUBMISSION/CORRECTION DEADLINES FOR PAYMENT DETERMINATIONS

Proposed CY data collection quarter	Data collection/submission quarterly reporting period	Quarterly review and correction periods and data submission deadlines for payment determination	
Quarter 1	January 1–March 31 * **	April 1–August 15 *	Deadline: August 15.* **
Quarter 2	April 1–June 30	July 1–November 15	Deadline: November 15.
Quarter 3	July 1–September 30	October 1–February 15	Deadline: February 15.
Quarter 4	October 1–December 31 * **	January 1–May 15 *	Deadline: May 15.* **

* The annual data submission time frame for the measure, Influenza Vaccination Coverage among Healthcare Personnel, is October 1 through March 31 of the subsequent year with a reporting deadline of May 15 in that subsequent year.

** For the measure, Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine, we refer readers to the proposals on data submission for this measure we are making in section VIII.C.9.d. of the preamble of this proposed rule. These proposals for the FY 2019 payment determination and for FY 2020 payment determination and subsequent years are illustrated in the tables in that section.

c. Proposed Timeline and Data Submission Mechanisms for the FY 2018 Payment Determination and Subsequent Years for Proposed New LTCH QRP Resource Use and Other Measures—Claims-Based Measures

The MSPB–PAC LTCH QRP measure; Discharge to Community-PAC LTCH QRP measure and Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP, which we have proposed in this proposed rule, are Medicare FFS claims-based measures. Because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, no additional information collection would be required from LTCHs. As discussed in section VIII.C.6. of the preamble of this proposed rule, these measures would use 2 years of claims-based data beginning with CY 2015 and CY 2016 claims to inform confidential feedback reports for LTCHs, and CYs 2016 and 2017 claims data for public reporting.

We are inviting public comments on this proposal.

d. Proposal To Revise the Previously Adopted Data Collection Period and Submission Deadlines for Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) for the FY 2019 Payment Determination and Subsequent Years

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53624 through 53627), we adopted the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure for the FY 2016 payment determination and subsequent years. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50858 through 50861), we finalized the data submission timelines and submission deadlines for the measures for FY 2016 and FY 2017 payment determinations. We refer readers to the FY 2013 and FY 2014 IPPS/LTCH PPS final rules for a more detailed discussion of the measure, timelines and deadlines.

In these previous rules, we finalized that LTCHs were required to perform data collection in alignment with the influenza vaccination season (IVS); that is, obtaining the vaccination status of patients who are in an LTCH for one or more days between the dates of October 1 of a given year through March 31 of the subsequent year, or what the CDC terms the Influenza Vaccination Season (IVS), but for only those patients whose corresponding admissions and discharges occurred during the IVS. Through analysis of the quality data submitted for this measure, we discovered that only requiring LTCH providers to submit patient Influenza vaccination data during the IVS (October 1 of a given year through March 31 of the subsequent year) inadvertently limits the data collection to only a subset of patients whose stays at an LTCH qualify for inclusion in the measure calculation. This measure is structured in such a way that all patients in an LTCH for one or more days during the IVS are included in the measure. For those patients, an LTCH should have the opportunity to demonstrate the Influenza vaccination status of these patients on either their LTCH CARE Data Set (LCDS) admission assessment or on their discharge assessment (planned, unplanned, or expired). By limiting data collection to only those assessments obtained during the IVS, per our previously finalized policy, CMS inadvertently excluded the collection of Influenza vaccination status data on those patients who were in an LTCH for at least one day during the IVS, but for whom the associated LCDS admission and/or discharge assessments occurred outside of the IVS (prior to October 1 or after March 31).

For these reasons, we are proposing that beginning with the FY 2019 payment determination and subsequent years, which includes the CY 2016/2017 IVS, data collection and submission for the measure Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) will be required year-round, thus including all patients in the LTCH one or more days during the IVS (October 1 of any given CY through March 31 of the subsequent CY), regardless of the associated LCDS admission and discharge dates. This includes, for example, a patient that is admitted September 15 of a given year, and discharged April 1 of the subsequent year (thus, in the LTCH during the IVS). This proposal would enable the important data collection necessary to indicate that a patient who had an admission or a discharge outside of the IVS, but was in the facility during the vaccination season, ensuring that the data collected and submitted to CMS is representative of the status of all patients within the IVS, rather than only a subset of those who had both admissions and discharges within the IVS.

Further, our proposal effectively changes the data collection and submission timeline for this measure to include 4 calendar quarters, that is based on the influenza *season* (July 1 of any given year through June 30 of the subsequent year), rather than on the calendar year. For the purposes of APU determination and for public reporting, data calculation and analysis uses data from an influenza vaccination season which takes place within the *influenza season* itself. While the influenza vaccination season is October 1 of a given year (or when the vaccine becomes available) through March 31 of the subsequent year, this timeframe rests within a greater time period of the *influenza season*, which spans 12 months—that is, July 1 of a given year through June 30 of the subsequent year, as defined by the CDC. Thus, for this measure, we utilize data from a timeframe of 12 months that mirrors the influenza season which is July 1 of a given year through June 30 of the subsequent year. In addition, for the APU determination, we review data submitted beginning on July 1 of the calendar year 2 years prior to the calendar year of the APU effective date and ending June 30 of the subsequent calendar year, one year prior to the calendar year of the APU effective date. For example, and as provided in the below for the FY 2020 (October 1, 2019) APU determination, we review data submission beginning July 1, 2017 through June 30, 2018 for the 2017/2018 influenza vaccination season (October 1, 2017 [or when the vaccine becomes available] through March 31, 2018), so as to capture all data that an LTCH will have submitted with regard to the 2017/2018 influenza vaccination season itself which resides within the associated influenza season. We will use assessment data from the influenza season so as to ensure full capture of vaccination status in the IVS that resides within the influenza season period, as well for public reporting. Further, because we enable the opportunity to review and correct data for all assessment based LCDS measures within the LTCH QRP, we continue to follow quarterly calendar data collection/submission quarterly reporting period(s) and their subsequent quarterly review and correction periods with data submission deadlines for public reporting and payment determinations. However, rather than using a standard CY timeframe, these quarterly data collection/submission periods and their subsequent quarterly review and correction periods and submission deadlines begin with CY quarter 3, July 1, of a given year and end CY quarter 2, June 30, of the following year.

The proposed revisions to the data collection period for the measure Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680), will ultimately have the effect of helping LTCHs capture Influenza vaccination data on any LTCH patients that were in their hospital for one or more days during the IVS, by ensuring that such patient's admission and discharge assessments, regardless of the date of those assessments, capture potential influenza vaccination data, and allow the appropriate inclusion of patients and thus the accurate calculation of data for this measure. Lastly, this clarification will also remove any ambiguity and ensure that LTCHs are receiving credit for recording the vaccination status of all patients that were in their hospital for at least one day during any given IVS, regardless of the date(s) of their admission and/or discharge.

We would like to note that in order to implement the newly proposed revision to the data collection timeframes and submission deadlines for this measure, the FY 2019 payment determination will only be based on three CY quarters, as this policy will not go into effect until October 1, 2016, which is the start of the 2016/2017 IVS. Because of this, we are not requiring LTCHs to respond to the Influenza vaccination items on the LCDS admission or discharge assessments that take place during Q3 2016 (7/1/16–9/30/16), as this quarter will occur prior to the effective date of this policy, if finalized. This is illustrated in the table for the FY 2019 payment determination, below. All subsequent payment determinations will be based on four CY quarters, as discussed above, beginning with Q3 of CY 2017 for the FY 2020 payment determination. This is illustrated in table for the FY 2020 payment determination and subsequent years, below.

FY 2019 PAYMENT DETERMINATION:* SUMMARY DETAILS ON DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR PREVIOUSLY ADOPTED QUALITY MEASURE, NQF #0680 PERCENT OF RESIDENTS OR PATIENTS WHO WERE ASSESSED AND APPROPRIATELY GIVEN THE SEASONAL INFLUENZA VACCINE

Submission method	Data collection/submission quarterly reporting period(s)	Quarterly review and correction periods data submission deadlines for payment determination*	APU determination affected
Finalized Measure: NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (77 FR 53624 through 53627)			
LTCH CARE Data Set/QIES ASAP System.	CY 16 10/1/16–12/31/16	1/1/2017–5/15/17 deadline	FY 2019.
	CY 17 Q1 1/1/17–3/31/17	4/1/2017–8/15/17 deadline.	
	CY 17 Q2 4/1/17–6/30/17	7/1/17–11/15/17 deadline.	

*This table refers to the FY 2019 payment determination only. We refer readers to the table below for all subsequent FY payment determinations for this measure.

FY 2020 PAYMENT DETERMINATION AND SUBSEQUENT YEARS: SUMMARY DETAILS ON DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR PREVIOUSLY ADOPTED QUALITY MEASURE, NQF #0680 PERCENT OF RESIDENTS OR PATIENTS WHO WERE ASSESSED AND APPROPRIATELY GIVEN THE SEASONAL INFLUENZA VACCINE

Submission method	Data collection/submission quarterly reporting period(s)	Quarterly review and correction periods data submission deadlines for payment determination*	APU determination affected
Finalized Measure: NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (77 FR 53624 through 53627)			
LTCH CARE Data Set/QIES ASAP System.	CY 17 Q3 7/1/17–9/30/17 Q3 (7/1–9/30)	10/1/17–2/15/18 deadline 10/1–2/15	FY 2020 Subsequent Years
	CY 17 Q4 10/1/17–12/31/17 Q4 (10/1–12/31)	1/1/2018–5/15/18 deadline 1/1–5/15	
	CY 18 Q1 1/1/18–3/31/18 Q1 (1/1–3/31)	4/1/2018–8/15/18 deadline 4/1–8/15	
	CY 18 Q2 4/1/18–6/30/18 Q2 (4/1–6/30)	7/1/18–11/15/18 deadline 7/1–11/15	

We are inviting comment on our proposal to revise the data collection and submission timeframe for the measure Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680), beginning with the FY 2019 payment determination and subsequent years.

e. Proposed Timeline and Data Submission Mechanisms for the Proposed LTCH QRP Quality Measure for the FY 2020 Payment Determination and Subsequent Years

As discussed in section VIII.C.7. of the preamble of this proposed rule, we are proposing that the data for the proposed quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, affecting the FY 2020 payment determination and subsequent years be collected by completing data elements that would be added to the LTCH CARE Data Set with submission through the QIES ASAP system. Data collection would begin on April 1, 2018. More information on LTCH reporting using the QIES ASAP system is located at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Technical-Information.html*.

For the FY 2020 payment determination, we are proposing to collect CY 2018 Q2 through Q4 data, that is, beginning with admissions on April 1, 2018 through discharges on December 31, 2018, to remain consistent with the usual April release schedule for the LTCH CARE Data Set, to give LTCHs sufficient time to update their systems so that they can comply with the new data reporting requirements, and to give CMS sufficient time to determine compliance for the FY 2020 payment determination. The proposed use of 3 quarters of data for the initial year of assessment data reporting in the LTCH QRP is consistent with the approach we used previously for the SNF, IRF, and Hospice QRPs.

The table below presents the proposed data collection period and data submission timelines for the new proposed LTCH QRP quality measure for the FY 2020 payment determination. We are inviting public comments on this proposal.

DETAILS ON THE PROPOSED DATA COLLECTION PERIOD AND DATA SUBMISSION TIMELINE FOR RESOURCE USE AND OTHER MEASURES AFFECTING THE FY 2020 PAYMENT DETERMINATION

Quality measure	Submission method	Data collection/submission quarterly reporting period	Quarterly review and correction periods and data submission deadlines for payment determination	APU determination affected
Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP.	LTCH CARE Data Set/QIES ASAP.	4/1/18–6/30/18 (Q2), 7/1/18–9/30/18 (Q3), 10/1/18–12/31/18 (Q4).	11/15/18 (Q2), 2/15/19 (Q3), 5/15/19 (Q4).	FY 2020.

Following the close of the reporting quarters for the FY 2020 payment determination, LTCHs would have the already established additional 4.5 months to correct their quality data and that the final deadline for correcting data for the FY 2020 payment determination would be May 15, 2019 for these measures. We are also proposing that for the FY 2021 payment determination and subsequent years, we would collect data using the calendar year reporting cycle as described in section VIII.C.9.c. of the preamble of this proposed rule, and illustrated in the table below. We are inviting public comments on this proposal.

PROPOSED DATA COLLECTION PERIOD AND DATA CORRECTION DEADLINES AFFECTING THE FY 2021 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Quality measure	Submission method	Proposed CY data collection quarter	Proposed data collection/submission quarterly reporting period	Proposed quarterly review and correction periods and data submission deadlines for payment determination
Drug regimen review conducted with follow-up for identified issues PAC LTCH QRP.	LTCH CARE Data Set/QIES ASAP.	Quarter 1	January 1–March 31	April 1–August 15.
		Quarter 2	April 1–June 30	July 1–November 15.
		Quarter 3	July 1–September 30	October 1–February 15.
		Quarter 4	October 1–December 31	January 1–May 15.

10. LTCH QRP Data Completion Thresholds for the FY 2016 Payment Determination and Subsequent Years

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50311 through 50314), we finalized LTCH QRP thresholds for completeness of LTCH data submissions. To ensure that LTCHs are meeting an acceptable standard for completeness of submitted data, we finalized the policy that, beginning with the FY 2016 payment determination and for each subsequent year, LTCHs must meet or exceed two separate data completeness thresholds: One threshold set at 80 percent for completion of quality measures data collected using the LTCH CARE Data Set submitted through the QIES and a second threshold set at 100 percent for quality measures data collected and submitted using the CDC's NHSN.

In addition, we stated that we would apply the same thresholds to all measures adopted as the LTCH QRP expands and LTCHs begin reporting data on previously finalized measure sets. That is, as we finalize new measures through the regulatory process, LTCHs will be held accountable for meeting the previously finalized data completion threshold requirements for each measure until such time that updated threshold requirements are proposed and finalized through a subsequent regulatory cycle.

Further, we finalized the requirement that an LTCH must meet or exceed both thresholds to avoid receiving a 2 percentage point reduction to their annual payment update for a given fiscal year, beginning with FY 2016 and for all subsequent payment updates. For a detailed discussion of the finalized LTCH QRP data completion requirements, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50311 through 50314). We are not proposing any changes to these policies.

11. LTCH QRP Data Validation Process for the FY 2016 Payment Determination and Subsequent Years

Validation is intended to provide added assurance of the accuracy of the data that will be reported to the public as required by sections 1886(m)(5)(E) and 1899B(g) of the Act. In the FY 2015 IPPS/LTCH PPS proposed rule (79 FR 28275 through 28276), we proposed, for the FY 2016 payment determination and subsequent years, a process to validate the data submitted for quality purposes. However, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50314 through 50316), we did not finalize the proposal; instead we decided to further explore suggestions from commenters before finalizing the LTCH data validation process that we proposed. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49752 through 49753), we did not propose any new policies related to data accuracy validation. In this proposed rule, we are not proposing a data validation policy because we are developing a policy that could be applied to several PAC quality reporting programs. We intend to propose a data validation policy through future rulemaking.

12. Proposed Change to Previously Codified LTCH QRP Submission Exception and Extension Policies

We refer readers to § 412.560(c) for requirements pertaining to submission exception and extension for the FY 2017 payment determination and subsequent years. At this time, we are proposing to revise § 412.560(c) to change the timing for submission of these exception and extension requests from 30 days to 90 days from the date of the qualifying event which is preventing an LTCH from submitting their quality data for the LTCH QRP. We are proposing the increased time allotted for the submission of the requests from 30 to 90 days to be consistent with other quality reporting programs; for example, the Hospital Inpatient Quality Reporting (IQR) Program is also proposing to extend the deadline to 90 days in section VIII.C.15.a. of the preamble of this proposed rule. We believe that this increased time will assist providers experiencing an event in having the time needed to submit such a request. With the exception of this one change, we are not proposing any additional changes to the exception and extension policies for the LTCH QRP at this time.

We are inviting public comments on the proposal to revise § 412.560(c) to change the timing for submission of these exception and extension requests from 30 days to 90 days from the date of the qualifying event which is preventing an LTCH from submitting their quality data for the LTCH QRP.

13. Previously Finalized LTCH QRP Reconsideration and Appeals Procedures

We refer readers to § 412.560(d) for a summary of our finalized reconsideration and appeals procedures for the LTCH QRP for FY 2017 payment determination and subsequent years. We are not proposing any changes to this policy. However, we wish to clarify that in order to notify LTCHs found to be non-compliant with the reporting requirements set forth for a given payment determination, we may include the QIES mechanism in addition to U.S. mail, and we may elect to utilize the MACs to administer such notifications.

14. Proposals and Policies Regarding Public Display of Measure Data for the LTCH QRP and Procedures for the Opportunity To Review and Correct Data and Information

a. Public Display of Measures

Section 1886(m)(5)(E) of the Act requires the Secretary to establish procedures for making the LTCH QRP data available to the public. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49753 through 49755), we finalized our proposals to display performance data for the LTCH QRP quality measures by fall 2016 on a CMS Web site, such as the *Hospital Compare*, after a 30-day preview period, and to give providers an opportunity to review and correct data submitted to the QIES ASAP system or to the CDC NHSN. The procedures for the opportunity to review and correct data are provided in the following section. In addition, we finalized the proposal to publish a list of LTCHs that successfully meet the reporting requirements for the applicable payment determination on the LTCH QRP Web site at: ***https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/ltch-quality-reporting/***. In the FY 2016 IPPS/LTCH PPS final rule, we also finalized that we would update the list after the reconsideration requests are processed on an annual basis.

Also, in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49753 through 49755), we finalized that the display of information for fall 2016 contains performance data on four quality measures:

- Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678);
- NHSN CAUTI Outcome Measure (NQF #0138);
- NHSN CLABSI Outcome Measure (NQF #0139); and
- All-Cause Unplanned Readmission Measure for 30-Days Post-Discharge from LTCHs (NQF #2512).

The measures Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), NHSN CAUTI Outcome Measure (NQF #0138), and NHSN CLABSI Outcome Measure (NQF #0139) are based on data collected beginning with the first quarter of 2015 or discharges beginning on January 1, 2015. With the exception of the All-Cause Unplanned Readmission Measure for 30-Days Post-Discharge from LTCHs (NQF #2512), rates are displayed based on 4 rolling quarters of data and would initially use discharges from January 1, 2015 through December 31, 2015 (CY 2015) for Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) and data collected from January 1, 2015 through December 31, 2015 for NHSN CAUTI Outcome Measure (NQF #0138) and NHSN CLABSI Outcome Measure (NQF #0139). For the readmissions measure, data will be publicly reported beginning with data collected for discharges beginning January 1, 2013, and rates would be displayed based on 2 consecutive years of data. For LTCHs with fewer than 25 eligible cases, we are proposing to assign the LTCH to a separate category: "The number of cases is too small (fewer than 25) to reliably tell how well the LTCH is performing." If an LTCH has fewer than 25 eligible cases, the LTCH's readmission rates and interval estimates would not be publicly reported for the measure.

Calculations for all four measures are discussed in detail in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49753 through 49755).

Pending the availability of data, we are proposing to publicly report data in CY 2017 on 4 additional measures beginning with data collected on these measures for the first quarter of 2015, or discharges beginning on January 1, 2015: (1) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716); (2) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717); and beginning with the 2015–16 influenza vaccination season these two measures; (3) Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431); and (4) Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680).

Standardized infection ratios (SIRs) for the Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716) and Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717) would be displayed based on 4 rolling quarters of data and would initially use MRSA Bacteremia and CDI events that occurred from January 1, 2015 through December 31, 2015 (CY 2015), for calculations. We are proposing that the display of these ratios would be updated quarterly.

Rates for the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) would be displayed for personnel working in the reporting facility October 1, 2015 through March 31, 2016. Rates for the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) would be displayed for patients in the LTCH during the influenza vaccination season, from October 1, 2015, through March 31, 2016. We are proposing that the display of these rates would be updated annually for subsequent influenza vaccination seasons.

Calculations for the MRSA Bacteremia and CDI Healthcare Associated Infection (HAI) measures adjust for differences in the characteristics of hospitals and patients using a Standardized Infection Ratio (SIR). The SIR is a summary measure that takes into account differences in the types of patients that a hospital treats. For a more detailed discussion about SIR, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49753). The MRSA Bacteremia and CDI SIRs may take into account the laboratory methods, bed size of the hospital, and other facility-level factors. It compares the actual number of HAIs in a facility or State to a national benchmark based on previous years of reported data and adjusts the data based on several factors. A confidence interval with a lower and upper limit is displayed around each SIR to indicate that there is a high degree of confidence that the true value of the SIR lies within that interval. A SIR with a lower limit that is greater than 1.0 means that there were more HAIs in a facility or State than were predicted, and the facility is classified as "Worse than the U.S. National Benchmark." If the SIR has an upper limit that is less than 1, the facility had fewer HAIs than were predicted and is classified as "Better than the U.S. National Benchmark." If the confidence interval includes the value of 1, there is no statistical difference between the actual number of HAIs and the number predicted, and the facility is classified as "No Different than U.S. National Benchmark." If the number of predicted infections is less than 1.0, the SIR and confidence interval are not calculated by CDC.

Calculations for the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) are based on reported numbers of personnel who received an influenza vaccine at the reporting facility or who provided written documentation of influenza vaccination outside the reporting facility. The sum of these two numbers is divided by the total number of personnel working at the facility for at least 1 day from October 1 through March 31 of the following year, and the result is multiplied by 100 to produce a compliance percentage (vaccination coverage). No risk adjustment is applicable to these calculations. More information on these calculations and measure specifications is available at: *http://www.cdc.gov/nhsn/pdfs/hps-manual/vaccination/4-hcp-vaccination-module.pdf*. We are proposing that this data would be displayed on an annual basis and would include data submitted by LTCHs for a specific, annual influenza vaccination season. A single compliance (vaccination coverage) percentage for all eligible healthcare personnel would be displayed for each facility.

We are inviting public comment on our proposal to begin publicly reporting in CY 2017 pending the availability of data on Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716); Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717); and Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431).

For the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) we are proposing to display rates annually based on the influenza season to avoid reporting for more than one influenza vaccination within a CY. For example, in 2017 we would display rates for the patient vaccination measure based on discharges starting on July 1, 2015, to June 30, 2016. We are proposing this approach because it includes the entire influenza vaccination season (October 1, 2015, to March 31, 2016).

Calculations for Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) would be based on patients meeting any one of the following criteria: Patients who received the influenza vaccine during the influenza season; patients who were offered and declined the influenza vaccine; and patients who were ineligible for the influenza vaccine due to contraindication(s). The facility's summary observed score would be calculated by combining the observed counts of all the criteria. This is consistent with the publicly reported patient influenza vaccination measure for *Nursing Home Compare*. In addition, for the patient influenza measure, we would exclude LTCHs with fewer than 20 stays in the measure denominator. For additional information on the specifications for this measure, we refer readers to the LTCH Quality Reporting Measures Information Web page at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html*.

We are inviting public comments on our proposal to begin publicly reporting the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) measure on discharges from July 1 of the previous calendar year to June 30 of the current calendar year. We are inviting comments on the public display of the measure Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #0680) in 2017 pending the availability of data.

In addition, we are requesting public comments on whether to include in the future, public display comparison rates based on CMS regions or U.S. census regions for Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678); All-Cause Unplanned Readmission Measure for 30-Days Post-Discharge from LTCHs (NQF #2512); and Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680) for CY 2017 public display.

b. Procedures for the Opportunity To Review and Correct Data and Information

Section 1899B(g) of the Act requires the Secretary to establish procedures for public reporting of LTCHs' performance, including the performance of individual LTCHs, on quality measures specified under section 1899B(c)(1) of the Act and resource use and other measures specified under section 1899B(d)(1) of the Act (collectively, IMPACT Act measures) beginning not later than 2 years after the applicable specified application date under section 1899B(a)(2)(E) of the Act. Under section 1899B(g)(2) of the Act, the procedures must ensure, including through a process consistent with the process applied under section 1886(b)(3)(B)(viii)(VII) of the Act, which refers to public display and review requirements in the Hospital IQR Program, that each LTCH has the opportunity to review and submit corrections to its data and information that are to be made public prior to the information being made public.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49754), and as illustrated in the second table in section VIII.C.9.e. of the preamble of this proposed rule, we finalized that once the provider has an opportunity to review and correct quarterly data related to measures submitted via the QIES ASAP system or CDC NHSN, we would consider the provider to have been given the opportunity to review and correct this data. We wish to clarify that although the correction of data (including claims) can occur after the submission deadline, if such corrections are made after a particular quarter's submission and correction deadline, such corrections will not be captured in the file that contains data for calculation of measures for public reporting purposes. To have publicly displayed performance data that is based on accurate underlying data, it will be necessary for LTCHs to review and correct this data before the quarterly submission and correction deadline.

In this proposed rule, we are restating and proposing additional details surrounding procedures that would allow individual LTCHs to review and correct their data and information on measures that are to be made public before those measure data are made public.

For assessment-based measures, we are proposing a process by which we would provide each LTCH with a confidential feedback report that would allow the LTCH to review its performance on such measures and, during a review and correction period, to review and correct the data the LTCH submitted to CMS via the CMS QIES ASAP system for each such measure. In addition, during the review and correction period, the LTCH would be able to request correction of any errors in the assessment-based measure rate calculations.

We are proposing that these confidential feedback reports would be available to each LTCH using the CASPER system. We refer to these reports as the LTCH Quality Measure (QM) Reports. We are proposing to provide monthly updates to the data contained in these reports as data become available. We are proposing to provide the reports so that providers would be able to view their data and information at both the facility and patient level for its quality measures. The CASPER facility level QM Reports may contain information such as the numerator, denominator, facility rate, and national rate. The CASPER patient-level QM Reports may contain individual patient information which would provide information related to which patients were included in the quality measures to identify any potential errors for those measures in which we receive patient-level data. Currently, we do not receive patient-level data on the CDC measure data received via the NHSN system. In addition, we would make other reports available in the CASPER system, such as LTCH CARE Data Set assessment data submission reports and provider validation reports, which would disclose the LTCH's data submission status providing details on all items submitted for a selected assessment and the status of records submitted.

We refer providers to the CDC NHSN system Web site for information on obtaining reports specific to NHSN submitted data at: *http://www.cdc.gov/nhsn/ltach/index.html*. Additional information regarding the content and availability of these confidential feedback reports would be provided on an ongoing basis on our Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html*.

As previously finalized in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49750 through 49752) and illustrated in the second table in section VIII.C.9.c. of the preamble of this proposed rule, LTCHs would have approximately 4.5 months after the reporting quarter to correct any errors of their assessment-based data (that appear on the CASPER-generated QM reports) and NHSN data used to calculate the measures. During the time of data submission for a given quarterly reporting period and up until the quarterly submission deadline, LTCHs could review and perform corrections to errors in the assessment data used to calculate the measures and could request correction of measure calculations. However, as already established, once the quarterly submission deadline occurs, the data is "frozen" and calculated for public reporting and providers can no longer submit any corrections. We would encourage LTCHs to submit timely assessment data during a given quarterly reporting period and review their data and information early during the review and correction period so that they can identify errors and resubmit data before the data submission deadline.

As noted above, the assessment data would be populated into the confidential feedback reports and we intend to update the reports monthly with all data that have been submitted and are available. We believe that the data collection/submission quarterly reporting periods plus 4.5 months to review and correct the data is sufficient time for LTCHs to submit, review and, where necessary, correct their data and information. These timeframes and deadlines for review and correction of such measures and data satisfy the statutory requirement that LTCHs be provided the opportunity to review and correct their data and information and are consistent with the informal process hospitals follow in the Hospital IQR Program.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49753 through 49755) we finalized the data submission/correction and review period. Also, we afford LTCHs a 30-day preview period prior to public display during which LTCHs may preview the performance information on their measures that will be made public. We would like to clarify that we will provide the *preview* report using the CASPER system, with which LTCHs are familiar. The CASPER preview reports inform providers of their performance on each measure which will be publicly reported. Please note that the CASPER *preview* reports for the reporting quarter will be available after the 4.5 month correction period and the applicable data submission/correction deadline have passed and are refreshed on a quarterly basis for those measures publicly reported quarterly, and annually for those measure publicly reported annually. We are proposing to give LTCHs 30 days to review the preview report beginning from the date on which they can access the report.

As already finalized, corrections to the underlying data would not be permitted during this time; however, LTCHs may ask for a correction to their measure calculations during the 30-day preview period. We are proposing that if CMS determines that the measure, as it is displayed in the preview report, contains a calculation error, we could suppress the data on the public reporting Web site, recalculate the measure and publish it at the time of the next scheduled public display date. This process would be consistent with informal processes used in the Hospital IQR Program. If finalized, we intend to utilize a subregulatory mechanism, such as our LTCH QRP Web site, to provide more information about the preview reports, such as when they will be made available and explain the process for how and when providers may ask for a correction to their measure calculations. We are inviting public comment on these proposals to provide preview reports using the CASPER system, giving LTCHs 30 days review the preview report and ask for a correction, and to use a subregulatory mechanism to explain the process for how and when providers may ask for a correction.

In addition to assessment-based measures and CDC measure data received via the NHSN system, we have also proposed claims-based measures for the LTCH QRP. The claims-based measures include those proposed to meet the requirements of the IMPACT Act as well as the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512) which was finalized for public display in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49753 through 49755). As noted in above, section 1899B(g)(2) of the Act requires prepublication provider review and correction procedures that are consistent with those followed in the Hospital IQR Program. Under the Hospital IQR Program's informal procedures, for claims-based measures, we provide hospitals 30 days to preview their claims-based measures and data in a preview report containing aggregate hospital-level data. We are proposing to adopt a similar process for the LTCH QRP.

Prior to the public display of our claims-based measures, in alignment with the Hospital IQR, HAC Reduction and Hospital VBP Programs, we are proposing to make available through the CASPER system, a confidential preview report that will contain information pertaining to claims-based measure rate calculations, for example, facility and national rates. The data and information would be for feedback purposes only and could not be corrected. This information would be accompanied by additional confidential information based on the most recent administrative data available at the time we extract the claims data for purposes of calculating the measures. Because the claims-based measures are recalculated on an annual basis, these confidential CASPER QM reports for claims-based measures will be refreshed annually. As previously finalized in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49753 through 49755), LTCHs will have 30 days from the date the preview report is made available in which to review this information.

The 30-day preview period is the only time when LTCHs would be able to see claims-based measures before they are publicly displayed. LTCHs would not be able to make corrections to underlying claims data during this preview period, nor would they be able to add new claims to the data extract. However, LTCHs may request that we correct our measure calculation if the LTCH believes it is incorrect during the 30-day preview period. We are proposing that if we agree that the measure, as it is displayed in the preview report, contains a calculation error, we could suppress the data on the public reporting Web site, recalculate the measure, and publish it at the time of the next scheduled public display date. This process would be consistent with informal policies followed in the Hospital IQR Program. If finalized, we intend to utilize a subregulatory mechanism, such as our LTCH QRP Web site, to explain the process for how and when providers may contest their measure calculations.

The proposed claims-based measures—The MSPB–PAC LTCH QRP; Discharge to Community—PAC LTCH QRP and Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP—use Medicare administrative data from hospitalizations for Medicare FFS beneficiaries. Public reporting of data would be based on 2 consecutive calendar years (CY) of data, which is consistent with the specifications of the proposed measures. We are proposing to create data extracts using claims data for the proposed claims based measures—The MSPB–PAC LTCH measure; Discharge to Community—PAC LTCH QRP and Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP—at least 90 days after the last discharge date in the applicable period, which we will use for the calculations. For example, if the last discharge date in the applicable period for a measure is December 31, 2017 for data collection January 1, 2016 through December 31, 2017, we would create the data extract on approximately March 31, 2018 at the earliest, and use that data to calculate the claims-based measures for that applicable period. Since LTCHs would not be able to submit corrections to the underlying claims snapshot nor add claims (for those measures that use LTCH claims) to this data set at the conclusion of the at least 90-day period following the last date of discharge used in the applicable period, at that time we would consider LTCH claims data to be complete for purposes of calculating the claims-based measures.

We are proposing that beginning with data that will be publicly displayed in 2018, claims-based measures will be calculated using claims data at least 90 days after the last discharge date in the applicable period, at which time we would create a data extract or snapshot of the available claims data to use for the measures calculation. This timeframe allows us to balance the need to provide timely program information to LTCHs with the need to calculate the claims-based measures using as complete a data set as possible. As noted, under this proposed procedure, during the 30-day preview period, LTCHs would not be able to submit corrections to the underlying claims data or to add new claims to the data extract. This is for two reasons: first, for certain measures, the claims data used to calculate the measures may not be derived from the LTCH's claims, but are from the claims of another provider. For example, the proposed measure Potentially Preventable 30-Day Post-Discharge Readmission Measure for LTCH QRP uses claims data submitted by the hospital to which the patient was readmitted, which may not be the LTCH. For the claims that are not those of the LTCH, the LTCH could not make corrections to them. Second, even where the claims used to calculate the measures are those of the LTCH, it would not be not possible to correct the data after it is extracted for the measures calculation. This is because it is necessary to take a static "snapshot" of the claims in order to perform the necessary measure calculations.

We seek to have as complete a data set as possible. We recognize that the proposed at least 90 day "run-out" period when we would take the data extract to calculate the claims-based measures, is less than the Medicare program's current timely claims filing policy under which providers have up to 1 year from the date of discharge to submit claims. We considered a number of factors in determining that the proposed at least 90 day run-out period is appropriate to calculate the claims-based measures. After the data extract is created, it takes several months to incorporate other data needed for the calculations (particularly in the case of risk-adjusted or episode-based measures). We then need to generate and check the calculations. Because several months lead time is necessary after acquiring the data to generate the claims-based calculations, if we were to delay our data extraction point to 12 months after the last date of the last discharge in the applicable period, we would not be able to deliver the calculations to LTCHs sooner than 18 to 24 months after the last discharge. We believe this would create an unacceptably long delay both for LTCHs and for us to deliver timely calculations to LTCHs for quality improvement.

We are inviting public comment on these proposals.

15. Proposed Mechanism for Providing Feedback Reports to LTCHs

Section 1899B(f) of the Act requires the Secretary to provide confidential feedback reports to PAC providers on their performance to the measures specified under sections 1899B(c)(1) and (d)(1) of the Act, beginning 1 year after the specified application date that applies to such measures and PAC providers. As discussed earlier, the reports we are proposing to provide for use by LTCHs to review their data and information would be confidential feedback reports that would enable LTCHs to review their performance on the measures required under the LTCH QRP. We are proposing that these confidential feedback reports would be available to each LTCH using the CASPER system. Data contained within these CASPER reports would be updated as previously described, on a monthly basis as the data become available except for our claims-based measures which are only updated on an annual basis.

We intend to provide detailed procedures to LTCHs on how to obtain their confidential feedback CASPER reports on the LTCH QRP Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html*.

We are proposing to use the CMS QIES ASAP system to provide quality measure reports in a manner consistent with how providers obtain various reports to date. The QIES ASAP system is a confidential and secure system with access granted to providers, or their designees.

We seek public comment on this proposal to satisfy the requirement to provide confidential feedback reports to LTCHs.

D. Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program

1. Background

a. Statutory Authority

Section 1886(s)(4) of the Act, as added and amended by sections 3401(f) and 10322(a) of the Affordable Care Act, requires the Secretary to implement a quality reporting program for inpatient psychiatric hospitals and psychiatric units.

Section 1886(s)(4)(A)(i) of the Act requires that, for FY 2014[275] and each subsequent fiscal year, the Secretary must reduce any annual update to a standard federal rate for discharges occurring during the fiscal year by 2.0 percentage points for any inpatient psychiatric hospital or psychiatric unit that does not comply with quality data submission requirements with respect to an applicable fiscal year.

As provided in section 1886(s)(4)(A)(ii) of the Act, the application of the reduction for failure to report under section 1886(s)(4)(A)(i) of the Act may result in an annual update of less than 0.0 percent for a fiscal year, and may result in payment rates under section 1886(s)(1) of the Act being less than the payment rates for the preceding year. In addition, section 1886(s)(4)(B) of the Act requires that the application of the reduction to a standard Federal rate update be noncumulative across fiscal years. Thus, any reduction applied under section 1886(s)(4)(A) of the Act will apply only with respect to the fiscal year rate involved and the Secretary may not take into account the reduction in computing the payment amount under the system described in section 1886(s)(1) of the Act for subsequent years.

Section 1886(s)(4)(C) of the Act requires that, for FY 2014 (October 1, 2013 through September 30, 2014) and each subsequent year, each psychiatric hospital and psychiatric unit must submit to the Secretary data on quality measures as specified by the Secretary. The data must be submitted in a form and manner and at a time specified by the Secretary. Under section 1886(s)(4)(D)(i) of the Act, unless the exception of subclause (ii) applies, measures selected for the quality reporting program must have been endorsed by the entity with a contract under section 1890(a) of the Act. The National Quality Forum (NQF) currently holds this contract.

Section 1886(s)(4)(D)(ii) of the Act provides an exception to the requirement for NQF endorsement of measures: in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

Section 1886(s)(4)(E) of the Act requires the Secretary to establish procedures for making public the data submitted by inpatient psychiatric hospitals and psychiatric units under the IPFQR Program. These procedures must ensure that a facility has the opportunity to review its data prior to the data being made public. The Secretary must report quality measures that relate to services furnished by the psychiatric hospitals and units on the CMS Web site.

b. Covered Entities

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53645), we established that the IPFQR Program's quality reporting requirements cover those psychiatric hospitals and psychiatric units paid under Medicare's IPF PPS (42 CFR 412.404(b)). Generally, psychiatric hospitals and psychiatric units within acute care and critical access hospitals that treat Medicare patients are paid under the IPF PPS. Consistent with prior rules, we continue to use the term "inpatient psychiatric facility" (IPF) to refer to both inpatient psychiatric hospitals and psychiatric units. This usage follows the terminology in our IPF PPS regulations at 42 CFR 412.402. For more information on covered entities, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53645).

c. Considerations in Selecting Quality Measures

Our objective in selecting quality measures is to balance the need for information on the full spectrum of care delivery and the need to minimize the burden of data collection and reporting. We have focused on measures that evaluate critical processes of care that have significant impact on patient outcomes and support CMS and HHS priorities for improved quality and efficiency of care provided by IPFs. We refer readers to section VIII.F.4.a. of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53645 through 53646) for a detailed discussion of the considerations taken into account in selecting quality measures.

Before being proposed for inclusion in the IPFQR Program, measures are placed on a list of measures under consideration, which is published annually by December 1 on behalf of CMS by the NQF. In compliance with section 1890A(a)(2) of the Act, measures that we are proposing for the IPFQR Program in this proposed rule were included in a publicly available document: "List of Measures under Consideration for December 1, 2015" (*http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81172*). The Measure Applications Partnership (MAP), a multi-stakeholder group convened by the NQF, reviews the measures under consideration for the IPFQR Program, among other Federal programs, and provides input on those measures to the Secretary. The MAP's 2016 recommendations for quality measures under consideration are captured in the following document: "Process and Approach for MAP Pre-Rulemaking Deliberations 2015–2016—Final Report, February 2016" (*http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81599*). We considered the input and recommendations provided by the MAP in selecting all measures for the IPFQR Program, including those discussed below.

2. Retention of IPFQR Program Measures Adopted in Previous Payment Determinations

The current IPFQR Program includes 16 mandatory measures. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53646 through 53652), we adopted 6 measures for the FY 2014 payment determination and subsequent years. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50889 through 50895), we added 2 measures for the FY 2016 payment determination and subsequent years. In the FY 2015

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[275] The statute uses the term "rate year" (RY). However, beginning with the annual update of the inpatient psychiatric facility prospective payment system (IPF PPS) that took effect on July 1, 2011 (RY 2012), we aligned the IPF PPS update with the annual update of the ICD–9–CM codes, effective on October 1 of each year. This change allowed for annual payment updates and the ICD–9–CM coding update to occur on the same schedule and appear in the same **Federal Register** document, promoting administrative efficiency. To reflect the change to the annual payment rate update cycle, we revised the regulations at 42 CFR 412.402 to specify that, beginning October 1, 2012, the RY update period would be the 12-month period from October 1 through September 30, which we refer to as a "fiscal year" (FY) (76 FR 26435). Therefore, with respect to the IPFQR Program, the terms "rate year," as used in the statute, and "fiscal year" as used in the regulation, both refer to the period from October 1 through September 30. For more information regarding this terminology change, we refer readers to section III. of the RY 2012 IPF PPS final rule (76 FR 26434 through 26435).

IPF PPS final rule (79 FR 45963 through 45974), we adopted another 2 measures for the FY 2016 payment determination and subsequent years, and finalized 4 quality measures for the FY 2017 payment determination and subsequent years. In the FY 2016 IPF PPS final rule (80 FR 46694 through 46714), we removed 1 measure beginning with the FY 2017 payment determination; we also adopted 5 measures and removed 2 measures beginning with the FY 2018 payment determination. We are retaining 15 of these previously adopted measures and proposing to update one measure, as discussed below.

3. Proposed Update to Previously Finalized Measure: Screening for Metabolic Disorders

In the FY 2016 IPF PPS final rule (80 FR 46709 through 46713), we finalized our proposal to include the Screening for Metabolic Disorders measure in the IPFQR Program for the FY 2018 payment determination and subsequent years. In that final rule, we described the denominator as IPF patients discharged with one or more routinely scheduled antipsychotic medications during the measurement period. We also listed the following denominator exclusions: (1) Patients for whom a screening could not be completed within the stay due to the patient's enduring unstable medical or psychological condition; and (2) patients with a length of stay equal to or greater than 365 days, or less than 3 days.

In the FY 2016 IPF PPS final rule (80 FR 46717 through 46718), we finalized the CMS global sample methodology for 10 IPFQR Program measures eligible for sampling, including the Screening for Metabolic Disorders measure. Seven of these 10 measures have denominator exclusions for patients with short length of stay within an IPF. Of these 7 measures, the Screening for Metabolic Disorders measure is the only one with an exclusion for less than 3 days; the other 6 all have denominator exclusions for length of stay less than or equal to 3 days. Therefore, we are proposing to update the length of stay exclusion for the Screening for Metabolic Disorders measure to exclude patients with a length of stay equal to or greater than 365 days, or less than or equal to 3 days. We anticipate that this update would reduce burden on IPFs, if it is finalized, because it would support the intent of the global sample to allow IPFs to use the same sample for as many measures as possible, by aligning the denominator exclusions.

We welcome public comments on this proposed denominator exclusion.

4. Proposed New Quality Measures for the FY 2019 Payment Determination and Subsequent Years

We are proposing two new measures for the FY 2019 payment determination and subsequent years:

- SUB–3 Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and the subset measure SUB–3a Alcohol & Other Drug Use Disorder Treatment at Discharge (NQF #1664) (SUB3 and SUB–3a); and
- Thirty-day all-cause unplanned readmission following psychiatric hospitalization in an IPF.

The sections below outline our rationale for proposing these measures.

a. SUB–3 Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and the Subset Measure SUB–3a Alcohol & Other Drug Use Disorder Treatment at Discharge (NQF #1664) (SUB–3 and SUB3a)

Individuals with mental illness experience substance use disorders (SUDs) at a much higher rate than the general population.[276] Nearly 18 percent of the 43.6 million adults aged 18 years and older who had a mental illness in 2013 met the criteria for a SUD. Of those who met the criteria for a SUD, 26.7 percent used illicit drugs.[277] Illicit drug use is particularly high among adults with serious mental illnesses.[278] Misuse and abuse of prescription drugs among individuals with mental illnesses, in particular opioids, are also of growing concern.

Individuals with co-occurring mental disorders and SUDs, the combination of one or more mental disorders and one or more SUDs, experience far more physical illnesses and episodes of care than individuals with a single diagnosis.[279] These co-occurring disorders tend to go undetected and untreated, especially among the elderly population, which experiences more adverse effects than the young adult population.[280] Treatment of only one disorder for individuals who have two or more mental and SUDs often leads to poor functioning and poor treatment compliance that inhibits full recovery, increases the risk of relapse, and can lead to other high-risk illnesses, such as coronary heart disease, diabetes, infections, and respiratory disease.[281] [282] Furthermore, individuals with undetected, untreated or undertreated co-occurring disorders are more likely to experience homelessness, incarceration, additional medical illness, suicide, and early death.[283]

Due to the prevalence of substance abuse among individuals with mental illness, and the negative effects therefrom, we believe it is imperative to assess IPFs' efforts to offer treatment options for patients who screen positive for drug and alcohol use. As described under the Measure Description section of the NQF Web page regarding this measure, the SUB–3 measure includes hospitalized patients age 18 years and older "who are identified with an alcohol or drug use disorder who receive or refuse at discharge a prescription for FDA-approved medications for alcohol or drug use disorder, OR who receive or refuse a referral for addictions treatment." [284] The SUB–3a subset measure includes hospitalized patients age 18 years and older "who receive a prescription for FDA-approved medications for alcohol or drug use disorder OR a referral for addictions treatment." [285] The numerator of the SUB–3 measure includes "patients who received or refused at discharge a prescription for medication for treatment of alcohol or drug use disorder OR received or refused a referral for addictions treatment." [286] The numerator of the SUB–3a subset measure includes "patients who received a prescription at discharge for medication for treatment of alcohol or drug use disorder OR a referral for addictions treatment." [287] The denominators of both the SUB–3 measure and SUB–3a subset measure include "hospitalized inpatients 18 years of age and older identified with an alcohol or drug use disorder" subject to a list of exclusions.[288] Further information on this measure, including the denominator exclusions, can be found in the measure detail sheet on the NQF's Web site (*http://www.qualityforum.org/QPS/1664*) or in the section of the Specifications Manual

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[276] National Institute on Drug Abuse (NIDA). "Comorbidity: Addiction and Other Mental Illnesses."

[277] SAMHSA. *Results from the 2014 National Survey on Drug Use and Health: Mental Health Findings.*

[278] Ibid.

[279] SAMHSA. "Mental and Substance Use Disorders."

[280] Robert Drake. "Dual Diagnosis and Integrated Treatment of Mental Illness and Substance Abuse Disorder."

[281] SAMHSA. "Mental and Substance Use Disorders."

[282] Mental Health Foundation. "Physical Health and Mental Health."

[283] SAMHSA. "Mental and Substance Use Disorders."

[284] NQF SUB–3 and SUB–3a Measure Specifications. Available at: *http://www.qualityforum.org/QPS/1664.*

[285] Ibid.

[286] Ibid.

[287] Ibid.

[288] Ibid.

for National Hospital Inpatient Quality Measures on Substance Use Measures at: *http://www.qualitynet.org/dcs/BlobServer?blobkey=id&blobnocache=true&blobwhere=1228890516540&blobheader=multipart%2Foctet-stream&blobheadername1=Content-Disposition&blobheadervalue1=attachment%3Bfilename%3D2.6.2_SUB_v5_1.pdf&blobcol=urldata&blobtable=MungoBlobs.*

We previously adopted the SUB–1 measure (Alcohol Use Screening (NQF #1661)) (78 FR 50890 through 50892) and the SUB–2 (Alcohol Use Brief Intervention Provided or Offered) and the subset measure SUB–2a (Alcohol Use Brief Intervention (NQF #1663) (SUB–2 and SUB–2a)) measure (80 FR 46699 through 46701). While the SUB–1 measure assesses "hospitalized patients 18 years of age and older who are screened during the hospital stay using a validated screening questionnaire for unhealthy alcohol use,"[289] the SUB–2 and SUB–2a measure assesses "hospitalized patients who screened positive for unhealthy alcohol use who received or refused a brief intervention during the hospital stay"[290] and "hospitalized patients 18 years and older who received the brief intervention during the hospital stay,"[291] respectively. The SUB–1 measure and the SUB–2 and SUB–2a measure combined provide a greater understanding of the rate at which patients are screened for potential alcohol abuse and the rate at which those who screen positive accept the offered interventions.

Despite the value created by the inclusion of the SUB–1 measure and the SUB–2 and SUB–2a measure in the IPFQR Program measure set, neither fully captures hospitalized patients 18 years of age and older with other SUDs because these measures focus on alcohol use only. In the past, commenters have urged CMS to include illicit and opioid drug screening in our measure set (80 FR 46701) stating that co-occurring substance use disorders are prevalent in many patients with psychiatric diagnoses and the SUB–3 and SUB–3a measure will ensure that patients continue to receive treatment after discharge.[292] While the SUB–3 and SUB–3a measure does not guarantee that patients would continue to receive treatment for substance use disorders after discharge, the addition of the SUB–3 and SUB–3a measure to the existing measure set would encourage IPFs to offer and provide FDA-approved medication OR a referral for addictions treatment to patients with co-occurring drug or alcohol use disorders at discharge. This measure would also provide information regarding the rate at which these treatment options are accepted by patients. The SUB–3 and SUB–3a measure also provides a fuller picture of the entire episode of care. In addition, aggregated data from the SUB–1 measure, SUB–2 and SUB–2a measure, and the SUB–3 and SUB–3a measure from each IPF would help provide patients with adequate consumer information to guide their decision-making process in selecting a treatment facility, specifically for patients that are diagnosed with a substance use disorder.

Furthermore, we believe that this measure set promotes the National Quality Strategy priority of Effective Prevention and Treatment for leading causes of mortality, starting with cardiovascular disease. It is notable that the high prevalence of SUDs among adults age 65 years and older contributes to serious medical conditions, including cardiovascular disease and liver disease. The proposed measure also supports HHS' Opioid Abuse Reduction Initiative to reduce prescription opioid and heroin related overdose, death, and dependence.[293] We also note that the addition of SUB–3 and SUB–3a in the measure set could encourage interventions and promote prevention of conditions that are associated with alcohol and drug use disorders.

For these reasons, we included the SUB–3 and SUB–3a measure in our "List of Measures under Consideration for December 1, 2015" (*http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81172*). The MAP provided input on the measure and supported its inclusion in the IPFQR Program in its report "Process and Approach for MAP Pre-Rulemaking Deliberations 2015–2016—Final Report, February 2016" available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=81599*. Moreover, this measure is NQF-endorsed for the IPF setting, in conformity with the statutory criteria for measure selection under section 1886(s)(4)(D)(i) of the Act.

Therefore, we are proposing to adopt the SUB–3 and SUB–3a measure for the FY 2019 payment determination and subsequent years. We welcome public comment on this proposal.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53657 through 53658) and FY 2014 IPPS/LTCH PPS final rule (78 FR 50901 through 50902), we finalized policies for population, sampling, and minimum case thresholds. In the FY 2016 IPF PPS final rule, we made one change to these requirements (80 FR 46717 through 46719) in finalizing a policy in which IPFs may take one, global sample for all measures for which sampling is permitted. This policy was adopted to decrease burden on IPFs and streamline policies and procedures. We are proposing to allow sampling for the SUB–3 and SUB–3a measure. Therefore, we are proposing to include the SUB3 and SUB–3a measure in the list of measures covered by the global sample. We welcome public comment on this proposal.

b. Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an IPF

The MAP, composed of national stakeholders, identified readmissions as a key gap area in the IPFQR Program in a January 2015 report.[294] A goal of the CMS Quality Strategy is to "promote effective communication and coordination of care" across different care settings and providers. In addition, readmission following discharge from IPFs is undesirable for patients because readmissions represent a deterioration in patients' mental and/or physical health status. Furthermore, an analysis of Medicare claims data for calendar years 2012 and 2013 showed that among the 716,174 IPF admissions for Medicare beneficiaries, more than 20 percent resulted in readmission to an IPF or a short-stay acute care hospital within 30 days of discharge.[295] Risk-standardized readmission rates ranged from 11 percent to 35 percent, indicating wide variation across IPFs and clear opportunity for improvement. Finally, MedPAC estimates of Medicare payments to IPFs in 2012 indicated that the average payment per discharge was nearly $10,000.[296] Therefore, reducing readmissions would substantially reduce costs. For these reasons, we developed a facility-level outcome measure of all-cause, unplanned readmissions following discharge from a qualifying IPF admission. This measure would provide an important indicator of the quality of care patients receive in the IPF setting.

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[289] NQF SUB–1 Measure Specifications.

[290] NQF SUB–2 and SUB–2a Measure Specifications.

[291] Ibid.

[292] 80 FR 46701.

[293] ASPE. "Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths."

[294] Process and Approach for MAP Pre-Rulemaking Deliberations. *Measure Applications Partnership*. 2015. Available at: *http://www.qualityforum.org/Setting_Priorities/Partnership/MAP_Final_Reports.aspx*.

[295] Inpatient Psychiatric Facility All-Cause Unplanned Readmission Measure: Draft Technical Report, November 23, 2015. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html#17*. (On this page, the file is listed as "Inpatient Psychiatric Facility (IPF) Outcome and Process Measure Development and Maintenance" under downloads.)

Although not all readmissions are preventable, there is evidence that improvements in the quality of care for patients in the IPF setting can reduce readmission rates which, in turn, would reduce costs to Medicare and the burden to patients and their caregivers. For example, a study of 30-day behavioral health readmissions using a multistate Medicaid database found that connecting patients to services they will need post-discharge can help prevent readmissions. A 1-percent increase in the percentage of patients receiving follow-up care within 7 days of discharge was associated with a 5 percent reduction in the probability of being readmitted.[297] Other studies have also found that transitional interventions such as pre- and post-discharge patient education, structured needs assessments, medication reconciliation/education, transition managers, and inpatient/outpatient provider communication have been effective in reducing early psychiatric readmissions. A systematic review of such interventions observed reductions of 13.6 percent to 37.0 percent of readmissions.[298]

The proposed readmission measure would complement the portfolio of facility-level, risk-standardized readmission measures in the acute care setting that CMS quality reporting and pay-for-performance programs currently use. These programs include, among others, the Hospital IQR Program, which requires facilities to report on condition-specific risk-standardized readmission measures (including Acute Myocardial Infarction (AMI), Heart Failure (HF), Pneumonia, and elective Hip/Knee replacements, among others).[299] In addition, the Hospital IQR Program requires reporting on a Hospital-Wide All-Cause Unplanned Readmissions measure (READM–30–HWR) as finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53521 through 53528). The Hospital Readmissions Reduction Program, a pay-for-performance program for subsection (d) hospitals or hospitals paid under section 1814(b)(3) of the Act, also uses risk-standardized condition-specific readmission measures (including AMI, HF, and Pneumonia, among others).[300]

The proposed IPF readmission measure, 30-day all-cause unplanned readmission following psychiatric hospitalization in an IPF, estimates a facility-level, risk-standardized readmission rate for unplanned, all-cause readmissions within 30 days of discharge from an IPF. Detailed information about the development of this measure as well as final measure specifications can be downloaded from the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html#17* (on this page, the file is listed as "Inpatient Psychiatric Facility (IPF) Outcome and Process Measure Development and Maintenance" under downloads.). The denominator for this measure includes Medicare FFS beneficiaries aged 18 years and older who are admitted to and discharged alive from an IPF with a principal diagnosis of a psychiatric disorder. Admissions to IPFs for nonpsychiatric disorders, which account for only 1.1 percent of admissions, were not included in the measure cohort because IPFs are expected to admit patients who need inpatient care for psychiatric causes.[301] Therefore, nonpsychiatric admissions could represent either admissions that were initiated for presumed or preliminary psychiatric diagnoses but later were changed to nonpsychiatric primary diagnoses during the admission or admissions with unreliable data.

Eligible index admissions require enrollment in Medicare Parts A and B for 12 months prior to the index admission, the month of admission, and at least 30 days post-discharge. Admissions to IPFs are excluded from the denominator if any of the following apply:

- Subsequent admission on day of discharge (Day 0) or within 2 days post-discharge (Day 1-Day 2) due to transfers to another inpatient facility on Day 0 or 1 or billing procedures for interrupted stays, which do not allow for identification of readmissions to the same IPF within 3 days;
- Patient discharged against medical advice (AMA) because the provider would not have an opportunity to provide optimal care; and
- Unreliable patient data (for example, has a death date but also admission afterwards).

The numerator for the IPF readmission measure is defined as any admission to an IPF or acute care hospital that occurs on or between days 3 and 30 post-discharge, except those considered planned by the CMS Planned Readmission Algorithm, Version 3.0.[302] The all-cause, unplanned, 30-day readmission rate is harmonized with other readmission measures that are endorsed by NQF and in use by CMS programs. For the timeframe for measurement, literature supports the connection between 30-day readmissions and the quality of care provided during the index admission.[303] [304] [305] [306] [307] This timeframe also supports interventions that have been developed on a wide range of patient populations that focus on reducing 30-day readmission rates.[308] [309] [310] [311] [312] Finally, a

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[296] Inpatient Psychiatric Facility Services Payment System. *MedPAC.* 2014. Available at: *http://www.medpac.gov/documents/payment-basics/inpatient-psychiatric-facility-services-payment-system-14.pdf.*

[297] Mark TL, Mark T, Tomic KS, et al. Hospital readmission among medicaid patients with an index hospitalization for mental and/or substance use disorder. *J Behav Health Serv Res.* 2013; 40(2):207–221.

[298] Vigod SN, Kurdyak PA, Dennis CL, et al. Transitional interventions to reduce early psychiatric readmissions in adults: Systematic review. *Br J Psychiatry.* 2013; 202(3):187–194.

[299] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/OutcomeMeasures.html.*

[300] 76 FR 51660 through 51676.

[301] Prospective Payment System for Inpatient Hospital Services. In: Services DoHaH, Ed. 42, Vol. 412, U.S. Government Publishing Office 2011:535–537.

[302] Horwitz LI, Grady JN, Zhang W, et al. 2015 Measure Updates and Specifications Report: Hospital-Wide All-Cause Unplanned Readmission Measure—Version 4.0. Centers for Medicare & Medicaid Services; 2015. Available in the Hospital Wide All Cause Readmission Updates folder at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[303] Hyland M. National Mental Health Benchmarking Project. In: Wendy Hoey, Whitecross MFaF, eds. Reducing 28 Day Readmission. Australian Mental Health Outcomes and Classification Network 2008:38.

[304] Boaz TL, Becker MA, Andel R, Van Dorn RA, Choi J, Sikirica M. Risk factors for early readmission to acute care for persons with schizophrenia taking antipsychotic medications. Psychiatric services (Washington, DC). 2013; 64(12):1225–1229.

[305] Zilber N, Hornik-Lurie T, Lerner Y. Predictors of early psychiatric rehospitalization: A national case register study. Isr J Psychiatry Relat Sci. 2011; 48(1):49–53.

[306] Lutterman T, Ganju V, Schacht L, Shaw R, Monihan K, et.al. Sixteen State Study on Mental Health Performance Measures. 2003.

[307] Carr VJ, Lewin TJ, Sly KA, et al. Adverse incidents in acute psychiatric inpatient units: rates, correlates and pressures. Aust N Z J Psychiatry. 2008; 42(4):267–282.

[308] Naylor M, Brooten D, Jones R, Lavizzo-Mourey R, Mezey M, Pauly M. Comprehensive discharge planning for the hospitalized elderly. A randomized clinical trial. Annals of internal medicine. 1994; 120(12):999–1006.

[309] Naylor MD, Brooten D, Campbell R, et al. Comprehensive discharge planning and home follow-up of hospitalized elders: A randomized clinical trial. JAMA. 1999; 281(7):613–620.

[310] van Walraven C, Seth R, Austin PC, Laupacis A. Effect of discharge summary availability during

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workgroup of relevant clinical experts agreed that the 30-day time period captures complications that may be attributable to the IPF.

An all-cause readmission rate was selected because it promotes a holistic approach to the treatment of patients with psychiatric disorders, who often have comorbid medical conditions. From the patient and caregiver perspective, these readmissions indicate a deterioration in the patient's condition. In addition, the relationship between principal discharge diagnosis of the index admission and the principal discharge diagnosis of the readmission may be complex and difficult to determine based only on principal diagnosis codes. For example, a patient discharged with bipolar disorder may be readmitted because of a suicide attempt or self-harm due to poorly controlled symptoms of bipolar disorder. A measure that looks only for readmissions with principal discharge diagnoses of bipolar disorder would miss these readmissions.

The IPF readmission measure uses Medicare FFS claims and enrollment data over a 24-month measurement period to calculate the measure results. Twenty-four months was determined to provide an adequate number of cases and reliable results. Because this measure is not limited to a single diagnosis, a 24-month measurement period gives sufficient sample size. The IPF measure had 4.2 percent of IPFs with fewer than 25 cases in the 24-month measurement period from January 2012 to December 2013. For comparison, the HWR measure had 3.8 percent of hospitals with fewer than 25 cases in the 12-month measurement period from July 2013 to June 2014.

We recognize that the risk of readmission is influenced by patient factors, so the measure is risk-adjusted to account for differences in the patients served across IPFs. Hierarchical logistic regression is used to estimate a risk standardized readmission rate for each facility. Factors considered in the risk-adjustment model include patient demographics, principal discharge diagnoses of the index admission, comorbidities in claims during the 12 months prior to the index admission or during the index admission with the exception of complications of care, and several risk variables specific to the IPF patient population. Risk factors were selected for inclusion in the final risk model if they were positively selected at least 70 percent of the time in a stepwise backward elimination process. The final risk model includes age, gender, 13 principal discharge diagnosis Agency for Healthcare Research and Quality (AHRQ) Clinical Classification Software (CCS) categories, 38 comorbidity CMS Hierarchical Condition Categories (CC), history of discharge against medical advice, history of suicide or self-harm, history of aggression, and the hospital as a random effect. For more information about factors used in calculating the risk-standardized readmission rate, we refer readers to the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html#17.* (On this page, the file is listed as "Inpatient Psychiatric Facility (IPF) Outcome and Process Measure Development and Maintenance" under downloads.)

We understand the importance of the role that sociodemographic status plays in the care of patients. However, we continue to have concerns about holding hospitals to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. We routinely monitor the impact of sociodemographic status on hospitals' results on our measures.

The NQF is currently undertaking a 2-year trial period in which new measures and measures undergoing maintenance review will be assessed to determine if risk-adjusting for sociodemographic factors is appropriate. For 2 years, NQF will conduct a trial of temporarily allowing inclusion of sociodemographic factors in the risk-adjustment approach for some performance measures. At the conclusion of the trial, NQF will issue recommendations on future permanent inclusion of sociodemographic factors. During the trial, measure developers are expected to submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model. Measure developers must submit information such as analyses and interpretations as well as performance scores with and without sociodemographic factors in the risk adjustment model. When this measure was submitted to NQF on January 29, 2016, this information was included.

Furthermore, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is conducting research to examine the effect of sociodemographic status on quality measures, resource use, and other measures under the Medicare program, as directed by the IMPACT Act. We will closely examine the findings of the ASPE reports and related Secretarial recommendations and consider how they apply to our quality programs at such time as they are available.

As part of the measure development process for this measure, we solicited public comments on the measure via the CMS Public Comment Web page. As part of our comment solicitation, we provided the Measure Information Form (MIF), Data Dictionary, and the Measure Technical Report to the public to inform their review of the measure. We accepted public comments from November 25, 2015 through December 11, 2015. The significant majority of stakeholders who provided comments on the measure design supported this measure because of the importance of measuring readmissions in this population. Commenters who provided input on the methodology agreed that it appears to be scientifically acceptable, and those who provided input on the feasibility agreed with our belief that the measure is feasible as designed. After review and evaluation of all the public comments received, we did not identify any areas in which the measure needed to be modified. For specific information regarding the comments we received, we refer readers to the CMS Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html#17.* (On this page, the file is listed as "Inpatient Psychiatric Facility (IPF) Outcome and Process Measure Development and Maintenance" under downloads.)

While section 1886(s)(4)(D)(ii) of the Act authorizes the Secretary to specify a measure that is not endorsed by NQF, the proposed IPF readmission measure was submitted to NQF for endorsement on January 29, 2016, and we anticipate the measure will receive endorsement prior to the release of the final rule. However, the exception to the requirement to specify an endorsed measure states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been

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post-discharge visits on hospital readmission. J Gen Intern Med. 2002; 17(3):186–192.

[311] Zhang J, Harvey C, Andrew C. Factors associated with length of stay and the risk of readmission in an acute psychiatric inpatient facility: a retrospective study. Aust N Z J Psychiatry. 2011; 45(7):578–585.

[312] Silva NC, Bassani DG, Palazzo LS. A case-control study of factors associated with multiple psychiatric readmissions. Psychiatric services (Washington, DC). 2009; 60(6):786–791.

endorsed or adopted by a consensus organization. We have reviewed NQF-endorsed and other consensus-endorsed measures related to all-cause unplanned readmissions and believe that none are appropriate to the inpatient psychiatric setting. Therefore, no equivalent readmission measure that is endorsed by a consensus organization is available for use in the IPFQR Program.

For the reasons stated above, we are proposing the IPF readmission measure described in this section for the FY 2019 payment determination and subsequent years. We welcome public comment on this proposal.

5. Summary of Proposed Measures for the FY 2019 Payment Determination and Subsequent Years

The measures that we are proposing to adopt for the IPFQR Program for the FY 2019 payment determination and subsequent years are set forth in the table below.

PROPOSED NEW IPFQR PROGRAM MEASURES FOR THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

National quality strategy priority	NQF No.	Measure ID	Measure
Effective Treatment and Prevention.	1664	SUB–3 and SUB–3a	SUB–3 Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB–3a Alcohol & Other Drug Use Disorder Treatment at Discharge.
Communication/Care Coordination.	N/A (Under review for endorsement).	N/A	Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an IPF.

If these measures are adopted, the number of measures for the FY 2019 IPFQR Program and subsequent years will total 18, as set forth in the table below.

PROPOSED AND FINALIZED MEASURES FOR FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

NQF No.	Measure ID	Measure
0640	HBIPS–2	Hours of physical restraint use.
0641	HBIPS–3	Hours of seclusion use.
0560	HBIPS–5	Patients discharged on multiple antipsychotic medications with appropriate justification.
0576	FUH	Follow-Up After Hospitalization for Mental Illness.
1661	SUB–1	Alcohol Use Screening.
1663	SUB–2 and SUB–2a	Alcohol Use Brief Intervention Provided or Offered and the subset measure Alcohol Use Brief Intervention.*
1651	TOB–1	Tobacco Use Screening.
1654	TOB–2 and TOB–2a	Tobacco Use Treatment Provided or Offered and the subset measure Tobacco Use Treatment.
1656	TOB–3 and TOB–3a	Tobacco Use Treatment Provided or Offered at Discharge and the subset measure Tobacco Use Treatment at Discharge.
1659	IMM–2	Influenza Immunization.
0647	N/A	Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care).
0648	N/A	Timely Transmission of Transition Record (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care).
N/A	N/A	Screening for Metabolic Disorders.
N/A	N/A	Influenza Vaccination Coverage Among Healthcare Personnel.
N/A	N/A	Assessment of Patient Experience of Care.
N/A	N/A	Use of an Electronic Health Record.
1664	SUB–3 and SUB–3a	Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and the subset measure Alcohol & Other Drug Use Disorder Treatment at Discharge.*
N/A (Under review for endorsement).	N/A	Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an IPF.*

* New measures proposed for the FY 2019 payment determination and future years.

6. Possible IPFQR Program Measures and Topics for Future Consideration

As we have indicated in prior rulemaking (79 FR 45974 through 45975), we seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the IPF setting. Therefore, through future rulemaking, we intend to propose new measures for adoption that will help further our goals of achieving better health care and improved health for Medicare beneficiaries who obtain inpatient psychiatric services through the widespread dissemination and use of quality information.

We welcome public comments on possible new measures.

7. Public Display and Review Requirements

We are proposing to change to how we specify the timeframes for public display of data and the associated preview period for IPFs to review the data that will be made public.

Under section 1886(s)(4)(E) of the Act, we are required to establish procedures for making the data submitted under the

IPFQR Program available to the public. Such procedures must ensure that an IPF has the opportunity to review its data that are to be made public prior to such data being made public. Section 1866(s)(4)(E) of the Act also provides that the Secretary must report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished in such hospitals on the CMS Web site.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50897 through 50898), we stated that we would publicly display the data submitted by IPFs for the IPFQR Program on a CMS Web site in April of each calendar year following the start of the respective payment determination year. For example, we publicly displayed the data for the FY 2015 payment determination in April 2015. We strive to publicly display data as soon as possible on a CMS Web site, as this provides consumers with healthcare information and furthers our goal of transparency. Therefore, we believe it is best to not specify in rulemaking the exact timeframe for publication, as doing so may prevent earlier publication. We are proposing, then, to make these data available as soon as it is feasible. We intend to make the data available on *Hospital Compare* on at least a yearly basis.

We also are required to give each IPF an opportunity to review its data before the data are made public. This purpose of this preview period is to ensure that each IPF is informed of the IPF level data that the public will be able to see for its facility, and to submit measure rate errors resulting from MS calculations of IPF submitted patient level claims and Web-based measure numerator and denominator data. It is not for the purpose of correcting an IPF's possible submission errors. As finalized in the 2015 IPF PPS final rule (79 FR 45976), IPFs have the entire data submission period to review and correct claims data element and Web-based measure numerator and denominator count data they have submitted to CMS. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50897 through 50898), we stated that the preview period would be 30 days and would begin approximately 12 weeks prior to the public display of the data.

Because we are proposing to make the data for the IPFQR Program available as soon as possible, and the timeframe for publication may change from year-to-year, we are proposing to no longer specify the dates for review in rulemaking, nor to specify in rulemaking that the preview period will begin approximately 12 weeks prior to publicly displaying the data. Instead, we are proposing to announce the exact timeframes through subregulatory guidance, including on a CMS Web site and/or on our applicable listservs. We also are proposing to continue our policy that the time period for review will be approximately 30 days in length.

As noted earlier, we wish to publicly display data as early as possible. For the FY 2017 payment determination, it may be technically feasible for us to display the data as early as December 2016. We previously finalized that the preview period would be 30 days and would be approximately 12 weeks prior to the public display date. However, in this case, 12 weeks prior to December 1, 2016 is in mid-September, which is 2 weeks before the usual effective date of the IPPS/LTCH PPS final rule. Therefore, for FY 2017 only, if it is technically feasible to display the data as early as December 2016, we are proposing a 2-week preview period that would start on October 1, 2016. However, as a courtesy, and to give IPFs 30 days for review if they so choose, we are proposing to provide IPFs with their data in mid-September. We believe that this proposal complies with prior policies while still allowing us to display data as soon as possible for the FY 2017 payment determination.

We are inviting public comment on these proposals.

8. Form, Manner, and Timing of Quality Data Submission

a. Procedural and Submission Requirements

We are not proposing any changes to the procedural and submission requirements for the FY 2019 payment determination and subsequent years, and we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50898 through 50899) for more information on these previously finalized requirements.

b. Proposed Change to the Reporting Periods and Submission Timeframes

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50901), we finalized requirements for reporting periods and submission timeframes for the IPFQR Program measures. In the FY 2016 IPF PPS final rule, we made one change to these requirements (80 FR 46715 and 46716). We refer readers to these rules for further information.

c. Population and Sampling

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53657 through 53658) and FY 2014 IPPS/LTCH PPS final rule (78 FR 50901 through 50902), we finalized policies for population, sampling, and minimum case thresholds. In the FY 2016 IPF PPS final rule, we made one change to these requirements (80 FR 46717 through 46719). We refer readers to these rules for further information.

d. Data Accuracy and Completeness Acknowledgement (DACA) Requirements

We are not proposing any changes to the DACA requirements and we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658) for more information on these requirements.

9. Reconsideration and Appeals Procedures

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658 through 53660), we adopted a reconsideration and appeals process, later codified at 42 CFR 412.434, by which an IPF can request a reconsideration of its payment update reduction if an IPF believes that its annual payment update has been incorrectly reduced for failure to meet all IPFQR Program requirements and, if dissatisfied with a decision made by CMS on its reconsideration request, may file an appeal with the Provider Reimbursement Review Board. We are not proposing any changes to the Reconsideration and Appeals Procedure and refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53658 through 53660) and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50953) for further details on the reconsideration process.

10. Exceptions to Quality Reporting Requirements

We are not proposing any changes to the exceptions to quality reporting requirements. For more information, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53659 through 53660), where we initially finalized the policy as "Waivers from Quality Reporting," and the FY 2015 IPF PPS final rule (79 FR 45978), where we renamed the policy as "Exceptions to Quality Reporting Requirements."

E. Clinical Quality Measurement for Eligible Hospitals and Critical Access Hospitals (CAHs) Participating in the EHR Incentive Programs in 2017

1. Background

The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA) authorizes incentive payments under Medicare and Medicaid for the adoption and meaningful use of certified electronic health record (EHR) technology (CEHRT). Eligible hospitals and CAHs may qualify for these incentive payments under Medicare (as authorized under sections 1886(n) and

1814(l) of the Act, respectively) if they successfully demonstrate meaningful use of CEHRT, which includes reporting on clinical quality measures (CQMs) using CEHRT.

Sections 1886(b)(3)(B) and 1814(l) of the Act also establish downward payment adjustments under Medicare, beginning with FY 2015, for eligible hospitals and CAHs that are not meaningful users of CEHRT for certain associated reporting periods. Section 1903(a)(3)(F)(i) of the Act establishes 100 percent Federal financial participation (FFP) to States for providing incentive payments to eligible Medicaid providers (described in section 1903(t)(2) of the Act) to adopt, implement, upgrade and meaningfully use CEHRT.

Under sections 1886(n)(3)(A) and 1814(l)(3)(A) of the Act and the definition of "meaningful EHR user" under 42 CFR 495.4, eligible hospitals and CAHs must report on CQMs selected by CMS using CEHRT, as part of being a meaningful EHR user under the Medicare EHR Incentive Program. The set of CQMs from which eligible hospitals and CAHs will report under the EHR Incentive Program beginning in FY 2014 is listed in Table 10 of the EHR Incentive Program Stage 2 final rule (77 FR 54083).

In order to further align CMS quality reporting programs for eligible hospitals and CAHs and avoid redundant or duplicative reporting among hospital programs, the Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017 (hereinafter referred to as the 2015 EHR Incentive Programs Final Rule)[313] (80 FR 62890) indicated our intent to address CQM reporting requirements for the Medicare and Medicaid EHR Incentive Programs for eligible hospitals and CAHs for 2016, 2017, and future years in the IPPS rulemaking. We believe that receiving and reviewing public comments for various CMS quality programs at one time while simultaneously finalizing the requirements for these programs would provide us with an opportunity to better align these programs for eligible hospitals and CAHs, allow more flexibility within the Medicare and Medicaid EHR Incentive Programs, and add overall value and consistency. To further achieve this goal, the 2015 Edition final rule (80 FR 62652) published by ONC indicated that it would address certification policy regarding the reporting of CQMs for eligible hospitals and CAHs in or in conjunction with the annual IPPS rulemaking to better align with the reporting goals of other CMS programs.

2. CQM Reporting for the Medicare and Medicaid EHR Incentive Programs in 2017

a. Background

In the EHR Incentive Program Stage 2 final rule, we outlined the CQMs available for use in the EHR Incentive Programs beginning in 2014 for eligible hospitals and CAHs in Table 10 at 77 FR 54083 through 54087. For the FY 2017 IPPS/LTCH PPS proposed rule, we are proposing to maintain the existing requirements established in earlier rulemaking for the reporting of CQMs under the EHR Incentive Programs in 2017, unless otherwise indicated in this proposed rule. These requirements include reporting on 16 CQMs covering at least 3 NQS domains for eligible hospitals and CAHs (77 FR 54079). For this section of the preamble of this proposed rule, the following proposed policies regarding the EHR Incentive Programs apply to both the Medicare and Medicaid EHR Incentive Programs with the exception of the submission period proposed policy.

As we expect to expand the current measures to align with the National Quality Strategy and the CMS Quality Strategy[314] and incorporate updated standards and terminology in current CQMs, including updating the electronic specifications for these CQMs, and creating de novo CQMs, we plan to expand the set of CQMs available for reporting under the EHR Incentive Programs in future years. We will continue to engage stakeholders to provide input on future proposals for CQMs as well as request comment on future electronic specifications for new and updated CQMs.

In addition, we are transitioning from the quality data model (QDM) expression language to the clinical quality language (CQL) specification, which defines a representation for the expression of clinical knowledge that can be used within both the clinical decision support (CDS) and CQM domains. The QDM logic is based on capabilities of the health level 7 (HL7) reference information model (RIM), which does not have significant ability to express mathematical logic such as addition, subtraction, division, and multiplication. The QDM requires multiple, often repetitious lines of logic to compare relationships among different activities, usually by indicating the time of one activity with the time of the other activity. Also, EHR software cannot easily interpret QDM logic to perform calculations without significant human interaction and interpretation. In general, the CQL is a mathematical expression language that can be parsed by software to calculate results. The CQL includes basic math and allows description of relationship among activities in a simple, direct manner, which significantly reduces the lines of logic. With a modest effort, it represents a change that is straightforward to learn and interpret compared to the existing QDM logic statements.

The CQL specification defines two components: CQL—author-friendly domain specific language; and expression logical model—computable extensible markup language (XML). The CQL leverages best practices and lessons learned from the quality data model, health e-decisions, and electronic CQM and clinical decision support (CDS) communities. The CQL is designed to work with any data model, more expressive and robust than the QDM logic, and is a HL7 draft standard for trial use (DSTU). The CQL includes: Datatypes; data retrieval and queries; timing phrases and operators; variable and function declaration; input parameters with default values; conditional logic, Boolean logic, and value comparison; simple arithmetic and aggregate functions; operations on valuesets, lists, intervals, sets and dates/times; and shared libraries. We anticipate the incorporation of the CQL into the CQM electronic specifications as we support the development and testing of this standard. We anticipate starting this work effort in 2016 with the expectation that extensive development and testing will continue, at minimum, through the fall of 2017. We will not implement CQL until the development and testing phases show success for utilization with the CQMs. We are engaging the participation of hospitals and other providers, health IT developer, measure developer, and other stakeholder communities as we undertake this effort at all stages of development and testing.

b. CQM Reporting Period for the Medicare and Medicaid EHR Incentive Programs in CY 2017

In the 2015 EHR Incentive Programs Final Rule (80 FR 62892 through 62893), beginning in CY 2017 and for subsequent years, we established a CQM reporting period of one full calendar year (consisting of four quarterly data reporting periods) for CQM reporting for eligible hospitals and CAHs participating in the Medicare and Medicaid EHR Incentive Programs, with a limited exception for providers demonstrating meaningful use for the first time under the Medicaid EHR Incentive Program, for whom the CQM reporting period is any continuous 90-day period within the calendar year. We believe that one full calendar year of data will result in more complete and accurate data. Providers will be able to submit one full calendar year of data for both the EHR Incentive Program and the Hospital IQR Program, thereby reducing the reporting burden. We continue to assess electronically submitted data for accuracy and reliability. If data are determined to be flawed, such data will be identified by CMS in order to preserve the integrity of data used for differentiating performance.

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[313] Medicare and Medicaid Programs: Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017; final rule (80 FR 62761 through 62955) ("2015 EHR Incentive Programs Final Rule").

[314] Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html.*

We also established a reporting period for CQMs of any continuous 90-day period within CY 2017 for eligible hospitals and CAHs that are demonstrating meaningful use for the first time in either the Medicare or Medicaid EHR Incentive Programs (80 FR 62892 through 62893). In summary, the following CQM reporting periods apply for eligible hospitals and CAHs participating in the Medicare and Medicaid EHR Incentive Programs in CY 2017. We are proposing the following submission periods for the Medicare EHR Incentive Program, as well as requirements for eligible hospitals and CAHs reporting CQMs electronically.

- Eligible hospitals and CAHs Reporting CQMs by Attestation:

++ For eligible hospitals and CAHs demonstrating meaningful use for the first time in 2017, the reporting period is any continuous 90-day period within CY 2017. The submission period for attestation is the 2 months following the close of the calendar year, ending February 28, 2018.

++ For eligible hospitals and CAHs that demonstrated meaningful use in any year prior to 2017, the reporting period is the full CY 2017 (consisting of four quarterly data reporting periods). The submission period for attestation is the 2 months following the close of the calendar year, ending February 28, 2018.

- Eligible hospitals and CAHs Reporting CQMs Electronically: For eligible hospitals and CAHs demonstrating meaningful use for the first time in 2017 or that have demonstrated meaningful use in any year prior to 2017, the reporting period is the full CY 2017 (consisting of four quarterly data reporting periods). The submission period for reporting CQMs electronically is the 2 months following the close of the calendar year, ending February 28, 2018.

In regard to the Medicaid EHR Incentive Program, we provide States with the flexibility to determine the submission periods for reporting CQMs.

For the reporting period in CY 2017, we are not proposing new CQMs. However, section 1886(n)(3)(B)(iii) of the Act requires that, in selecting measures for eligible hospitals and CAHs for the Medicare EHR Incentive Program, and establishing the form and manner for reporting measures, the Secretary shall seek to avoid redundant or duplicative reporting with reporting otherwise required, including reporting under section 1886(b)(3)(B)(viii) of the Act, the Hospital IQR Program. In the interest of avoiding redundant or duplicative reporting with the Hospital IQR Program, we are proposing to remove 13 CQMs from the set of CQMs available for eligible hospitals and CAHs to report for the EHR Incentive Programs, beginning with the reporting periods in CY 2017. We are proposing to remove such measures for both the Medicare and Medicaid EHR Incentive Programs.

We believe that a coordinated reduction in the overall number of CQMs reported electronically in both the Hospital IQR and the Medicare and Medicaid EHR Incentive Programs would reduce burdens and challenges associated with electronic reporting for hospitals and improve the quality of reported data by enabling hospitals to focus on a smaller, more specific subset of electronic CQMs. For the list of measures we are proposing to remove from the Hospital IQR Program and the Medicare and Medicaid EHR Incentive Programs, as well as the rationale in support of our proposals to remove these measures, we refer readers to section XVIII.A.3.b.(3) of the preamble of this proposed rule. All of the remaining measures listed in Table 10 of the EHR Incentive Program Stage 2 final rule (77 FR 54083 through 54087) would be available for eligible hospitals and CAHs to report for the Medicare and Medicaid EHR Incentive Programs. From that available set of measures, we are proposing the following reporting criteria for eligible hospitals and CAHs beginning with the reporting periods in CY 2017:

- For attestation: If only participating in the EHR Incentive Program, report on all 16 available CQMs.
- For electronic reporting—

++ If only participating in the EHR Incentive Program, report on 15 of the 16 available CQMs (the Outpatient Quality Reporting (OQR) Program CQM (Emergency Department (ED)–3, NQF 0496) among the 16 available CQMs is not required to be reported on for electronic reporting, in which 15 of the 16 available CQMs can be selected to meet this reporting requirement); or

++ If participating in the EHR Incentive Program and the Hospital IQR Program, report on all 15 available CQMs (the electronic reporting of the Outpatient Quality Reporting (OQR) Program CQM (ED–3, NQF 0496) is not applicable when reporting on CQMs for both programs, which results in the reporting of 15 available CQMs).

We also considered an alternative proposal to require eligible hospitals and CAHs to select and report electronically on 8 CQMs for the reporting periods in CY 2017 and all available CQMs beginning with the reporting periods in CY 2018. Section VIII.A.8.a. of the preamble of this proposed rule further outlines this considered alternative proposal. Our intent is to align, to the extent possible, the EHR Incentive Program reporting requirements with the Hospital IQR Program reporting requirements established in the final rule. We believe that the alignment of these programs will serve to reduce hospital reporting burden and encourage the adoption and meaningful use of CEHRT by eligible hospitals and CAHs. We are inviting public comment on these proposals.

c. CQM Reporting Form and Method for the Medicare EHR Incentive Program in 2017

As finalized in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49759 through 40760), we removed the QRDA–III as an option for reporting under the Medicare EHR Incentive Program for eligible hospitals and CAHs. For the reporting periods in 2016 and future years, we are requiring QRDA–I for CQM electronic submissions for the Medicare EHR Incentive Program. As noted in the FY 2016 IPPS/LTCH PPS final rule (80 FR 40760), States would continue to have the option, subject to our prior approval, to allow or require QRDA–III for CQM reporting.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49578 through 49579), we established the following options for CQM submission for eligible hospitals and CAHs in the Medicare EHR Incentive Program for the reporting periods in 2017:

- Eligible hospital and CAH options for Medicare EHR Incentive Program participation *(single program participation)*—

++ Option 1: Attest to CQMs through the EHR Registration & Attestation System; or

++ Option 2: Electronically report CQMs through QualityNet Portal.

- Eligible hospital and CAH options for electronic reporting for multiple programs *(for example, EHR Incentive Program plus Hospital IQR Program participation)*—electronically report through QualityNet Portal.

As stated in the 2015 EHR Incentive Programs Final Rule (80 FR 62894), in 2017, eligible hospitals and CAHs have two options to report CQM data, either through attestation or use of established methods for electronic reporting where feasible. However, starting in 2018, eligible hospitals, and CAHs participating in the Medicare EHR Incentive Program must electronically report CQMs using CEHRT where feasible; and attestation to CQMs will no longer be an option except in certain circumstances where electronic reporting is not feasible. Therefore, we encourage eligible hospitals and CAHs to begin electronically reporting CQMs as soon as feasible.

For the Medicaid EHR Incentive Program, States will continue to be responsible for determining whether and how electronic reporting of CQMs would occur, or if they wish to allow reporting through attestation. Any changes that States make to their CQM reporting methods must be submitted through the State Medicaid Health IT Plan (SMHP) process for CMS review and approval prior to being implemented.

We are proposing to continue our policy that electronic submission of CQMs will require the use of the most recent version of the CQM electronic specification for each CQM to which the EHR is certified. In the event that an eligible hospital or CAH has certified EHR technology that is certified to the 2014 Edition and not certified to all 16 CQMs that would be available for reporting in 2017 under our proposals, we are proposing to require that an eligible hospital or CAH would need to have its EHR technology certified to all such CQMs in order to meet the reporting requirements for 2017. For electronic reporting in 2017, this means eligible hospitals and CAHs would be required to use the Spring 2017 version of the CQM electronic specifications available on the eCQI Resource Center Web page (*https://ecqi.healthit.gov/*). We are seeking public comment on this proposal.

As noted in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49759), an EHR certified for CQMs under the 2014 Edition certification criteria does not need to be recertified each time it is updated to a more recent version of the CQMs. We are proposing to accept the use of CEHRT certified to ONC's 2014 or 2015 Edition for CQM reporting in 2017. Certification to the 2015 Edition is expected to be available in 2016. (For further information on CQM reporting, we refer readers to the EHR Incentive Program Web site where guides and tip sheets are available for each reporting option (*http://www.cms.gov/ehrincentiveprograms*).) As noted in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49759), we encourage health IT developers to test any updates, including any updates to the CQMs and CMS reporting requirements based on the CMS Implementation Guide for Quality Reporting Document Architecture (QRDA) Category I and Category III (CMS Implementation Guide for QRDA) for Eligible Professional Programs and Hospital Quality Reporting (HQR), on an annual basis.

The form and method of electronic submission are further explained in subregulatory guidance and the certification process. For example, the following documents are updated annually to reflect the most recent CQM electronic specifications: The CMS Implementation Guide for QRDA; program specific performance calculation guidance; and CQM electronic specifications and guidance documents. These documents are located on the eCQI Resource Center Web page: (*https://ecqi.healthit.gov/*).

We are inviting public comments on these proposals.

IX. MedPAC Recommendations

Under section 1886(e)(4)(B) of the Act, the Secretary must consider MedPAC's recommendations regarding hospital inpatient payments. Under section 1886(e)(5) of the Act, the Secretary must publish in the annual proposed and final IPPS rules the Secretary's recommendations regarding MedPAC's recommendations. We have reviewed MedPAC's March 2016 "Report to the Congress: Medicare Payment Policy" and have given the recommendations in the report consideration in conjunction with the proposed policies set forth in this proposed rule. MedPAC recommendations for the IPPS for FY 2017 are addressed in Appendix B to this proposed rule.

For further information relating specifically to the MedPAC reports or to obtain a copy of the reports, contact MedPAC at (202) 653–7226, or visit MedPAC's Web site at: *http://www.medpac.gov*.

X. Other Required Information

A. Requests for Data From the Public

In order to respond promptly to public requests for data related to the prospective payment system, we have established a process under which commenters can gain access to raw data on an expedited basis. Generally, the data are now available on compact disc (CD) format. However, many of the files are available on the Internet at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Data files and the cost for each file, if applicable, are listed later in this section. Anyone wishing to purchase data tapes, cartridges, or diskettes should submit a written request along with a company check or money order (payable to CMS–PUF) to cover the cost to the following address: Centers for Medicare & Medicaid Services, Public Use Files, Accounting Division, P.O. Box 7520, Baltimore, MD 21207–0520, (410) 786–3691. Files on the Internet may be downloaded without charge.

1. CMS Wage Data Public Use File

This file contains the hospital hours and salaries from Worksheet S–3, Parts II and III from FY 2013 Medicare cost reports used to create the proposed FY 2017 prospective payment system wage index. Multiple versions of this file are created each year. For a complete schedule on the release of different versions of this file, we refer readers to the wage index schedule in section III.M. of the preamble of this proposed rule.

Processing year	Wage data year	PPS fiscal year
2016	2013	2017
2015	2012	2016
2014	2011	2015
2013	2010	2014
2012	2009	2013
2011	2008	2012
2010	2007	2011
2009	2006	2010
2008	2005	2009
2007	2004	2008

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html*.

Periods Available: FY 2007 through FY 2017 IPPS Update.

2. CMS Occupational Mix Data Public Use File

This file contains the CY 2013 occupational mix survey data to be used to compute the occupational mix adjustment wage indexes. Multiple versions of this file are created each year. For a complete schedule on the release of different versions of this file, we refer readers to the wage index schedule in section II.M. of the preamble of this proposed rule.

Media: Internet at: *https://www.cms.gov/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html.*

Period Available: FY 2017 IPPS Update.

3. Provider Occupational Mix Adjustment Factors for Each Occupational Category Public Use File

This file contains each hospital's occupational mix adjustment factors by occupational category. Two versions of these files are created each year to support the rulemaking.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-AService-Payment/AcuteInpatientPPS/Wage-Index-Files.html.*

Period Available: FY 2017 IPPS Update.

4. Other Wage Index Files

CMS releases other wage index analysis files after each proposed and final rule.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html.*

Periods Available: FY 2005 through FY 2017 IPPS Update.

5. FY 2017 IPPS SSA/FIPS CBSA State and County Crosswalk

This file contains a crosswalk of State and county codes used by the Social Security Administration (SSA) and the Federal Information Processing Standards (FIPS), county name, and a list of Core-Based Statistical Areas (CBSAs).

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Period Available: FY 2017 IPPS Update.

6. HCRIS Cost Report Data

The data included in this file contain cost reports with fiscal years ending on or after September 30, 1996. These data files contain the highest level of cost report status.

Media: Internet at: *http://www.cms.hhs.gov/CostReports/02_HospitalCostReport.asp.*

(We note that data are no longer offered on a CD. All of the data collected are now available free for download from the cited Web site.)

7. Provider-Specific File

This file is a component of the PRICER program used in the MAC's system to compute DRG/MS–DRG payments for individual bills. The file contains records for all prospective payment system eligible hospitals, including hospitals in waiver States, and data elements used in the prospective payment system recalibration processes and related activities. Beginning with December 1988, the individual records were enlarged to include pass-through per diems and other elements.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ProspMedicareFeeSvcPmtGen/Index.html.*

Period Available: Quarterly Update.

8. CMS Medicare Case-Mix Index File

This file contains the Medicare case-mix index by provider number as published in each year's update of the Medicare hospital inpatient prospective payment system. The case-mix index is a measure of the costliness of cases treated by a hospital relative to the cost of the national average of all Medicare hospital cases, using DRG/MS–DRG weights as a measure of relative costliness of cases. Two versions of this file are created each year to support the rulemaking.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Periods Available: FY 1985 through FY 2017.

9. MS–DRG Relative Weights (Also Table 5—MS–DRGs)

This file contains a listing of MS–DRGs, MS–DRG narrative descriptions, relative weights, and geometric and arithmetic mean lengths of stay for each fiscal year. Two versions of this file are created each year to support the rulemaking.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Periods Available: FY 2005 through FY 2017 IPPS Update.

10. IPPS Payment Impact File

This file contains data used to estimate payments under Medicare's hospital impatient prospective payment systems for operating and capital-related costs. The data are taken from various sources, including the Provider-Specific File, HCRIS Cost Report Data, MedPAR Limited Data Sets, and prior impact files. The data set is abstracted from an internal file used for the impact analysis of the changes to the prospective payment systems published in the **Federal Register**. Two versions of this file are created each year to support the rulemaking.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Historical-Impact-Files-for-FY-1994-through-Present.html.*

Periods Available: FY 1994 through FY 2017 IPPS Update.

11. AOR/BOR Tables

This file contains data used to develop the MS–DRG relative weights. It contains mean, maximum, minimum, standard deviation, and coefficient of variation statistics by MS–DRG for length of stay and standardized charges. The BOR tables are "Before Outliers Removed" and the AOR is "After Outliers Removed." (Outliers refer to statistical outliers, not payment outliers.)

Two versions of this file are created each year to support the rulemaking.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Periods Available: FY 2005 through FY 2017 IPPS Update.

12. Prospective Payment System (PPS) Standardizing File

This file contains information that standardizes the charges used to calculate relative weights to determine payments under the hospital inpatient operating and capital prospective payment systems. Variables include wage index, cost-of-living adjustment (COLA), case-mix index, indirect medical education (IME) adjustment, disproportionate share, and the Core-Based Statistical Area (CBSA). The file supports the rulemaking.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Period Available: FY 2017 IPPS Update.

13. Hospital Readmissions Reduction Program Supplemental File

This file contains information on the calculation of the Hospital Readmissions Reduction Program (HRRP) payment adjustment. Variables include the proxy excess readmission ratios for acute myocardial infarction (AMI), pneumonia (PN) and heart failure (HF), coronary obstruction pulmonary disease (COPD), total hip arthroplasty (THA)/total knee arthroplasty (TKA), and coronary artery bypass grafting (CABG) and the proxy readmissions payment adjustment for each provider included in the program. In addition, the file contains information on the number of cases for each of the applicable conditions excluded in the calculation of the readmission payment adjustment factors. It also contains MS–DRG relative weight information to estimate the payment adjustment factors. The file supports the rulemaking.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Period Available: FY 2017 IPPS Update.

14. Medicare Disproportionate Share Hospital (DSH) Supplemental File

This file contains information on the calculation of the uncompensated care payments for FY 2017. Variables include a hospital's SSI days and Medicaid days used to determine a hospital's share of uncompensated care payments, total uncompensated care payments and estimated per claim uncompensated care payment amounts. The file supports the rulemaking.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Period Available: FY 2017 IPPS Update.

B. Collection of Information Requirements

1. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In this proposed rule, we are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

2. ICRs for Add-On Payments for New Services and Technologies

Section II.H.1. of the preamble of this proposed rule discusses add-on payments for new services and technologies. Specifically, this section states that applicants for add-on payments for new medical services or technologies for FY 2018 must submit a formal request. A formal request includes a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement. In addition, the request must contain a significant sample of the data to demonstrate that the medical service or technology meets the high-cost threshold.

We believe the burden associated with this requirement is exempt from the PRA under 5 CFR 1320.3(c), which defines the agency collection of information subject to the requirements of the PRA as information collection imposed on 10 or more persons within any 12-month period. This information collection does not impact 10 or more entities in a 12-month period. For FYs 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, and 2017, we received 1, 4, 5, 3, 3, 5, 5, 7, 9, and 9 applications, respectively.

3. ICRs for the Occupational Mix Adjustment to the Proposed FY 2017 Wage Index (Hospital Wage Index Occupational Mix Survey)

Section III.E. of the preamble of this proposed rule discusses the occupational mix adjustment to the proposed FY 2017 wage index While the preamble does not contain any new ICRs, we note that there is an OMB approved information collection request associated with the hospital wage index.

Section 304(c) of Public Law 106–554 amended section 1886(d)(3)(E) of the Act to require us to collect data at least once every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program in order to construct an occupational mix adjustment to the wage index. We collect the data via the occupational mix survey.

The burden associated with this information collection requirement is the time and effort required to collect and submit the data in the Hospital Wage Index Occupational Mix Survey to CMS. The aforementioned burden is subject to the PRA; it is currently approved under OMB control number 0938–0907.

4. Hospital Applications for Geographic Reclassifications by the MGCRB

Section III.J.2. of the preamble of this proposed rule discusses proposed changes to the wage index based on hospital reclassifications. As stated in that section, under section 1886(d)(10) of the Act, the MGCRB has the authority to accept short-term IPPS hospital applications requesting geographic reclassification for wage index and to issue decisions on these requests by hospitals for geographic reclassification for purposes of payment under the IPPS.

The burden associated with this application process is the time and effort necessary for an IPPS hospital to complete and submit an application for reclassification to the MGCRB. The burden associated with this requirement is subject to the PRA. It is currently approved under OMB control number 0938–0573.

5. ICRs for the Notice of Observation Treatment by Hospitals and CAHs

In section IV.L. of the preamble of this proposed rule, we discuss our proposed implementation of the NOTICE Act (Pub. L. 114–42), which amended section 1866(a)(1) of the Act to require hospitals and CAHs to provide written and oral notification to Medicare beneficiaries receiving observation services as outpatients for more than 24 hours. We have developed a standardized format for the notice (the MOON), which would be disseminated during the normal course of related business activities. The proposed standardized notice discussed in this proposed rule is simultaneously being subject to public review and comment through the Office of Management and Budget (OMB) Paperwork Reduction Act process before implementation.

We estimate that it will take hospitals and CAHs 5 minutes (0.0833 hour) to complete and deliver each notice. In 2014, there were approximately 977,000 claims for Medicare outpatient observation services lasting greater than 24 hours furnished by 6,142 hospitals and CAHs.[315] The annual hour burden is estimated to be 81,384 (977,000 responses × 0.0833 hour). To derive average cost, we used data from the U.S. Bureau of Labor Statistics' May 2014 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, we used the mean hourly wage of $33.55 and the cost of fringe benefits, $33.55 (calculated at 100 percent of salary), to determine an adjusted hourly wage of $67.10. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonable accurate estimation method. The cost per response is approximately $5.59 based on an hourly salary rate of $67.10 (U.S. Bureau of Labor Statistics' May 2013 National Occupational Employment and Wage Estimates for nursing) and the 5-minute response estimate. By multiplying the annual responses by $5.59, the annual cost burden estimate is $5,461,430 (977,000 responses × $5.59) or approximately $889.19 per hospital or CAH ($5,461,430/6,142).

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[315] Source: CMS Office of Enterprise and Data Analytics.

6. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program

The Hospital IQR Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment (RHQDAPU) Program) was originally established to implement section 501(b) of the MMA, Public Law 108–173. This program expanded our voluntary Hospital Quality Initiative. The Hospital IQR Program originally consisted of a "starter set" of 10 quality measures. The collection of information associated with the original starter set of quality measures was previously approved under OMB control number 0938–0918. All of the information collection requirements previously approved under OMB control number 0938–0918 have been combined with the information collection request currently approved under OMB control number 0938–1022. We no longer use OMB control number 0938–0918.

We added additional quality measures to the Hospital IQR Program and submitted the information collection request to OMB for approval. This expansion of the Hospital IQR Program measures was part of our implementation of section 5001(a) of the Deficit Reduction Act of 2005 (DRA). Section 1886(b)(3)(B)(viii)(III) of the Act, added by section 5001(a) of the DRA, requires that the Secretary expand the "starter set" of 10 quality measures that were established by the Secretary as of November 1, 2003, to include measures "that the Secretary determines to be appropriate for the measurement of the quality of care furnished by hospitals in inpatient settings." The burden associated with these reporting requirements is currently approved under OMB control number 0938–1022.

In section VIII.A.3.b. of the preamble of this proposed rule, we are proposing to remove 13 eCQM versions of measures, 2 "topped out" chart-abstracted measures, and 2 structural measures, beginning with the FY 2019 payment determination. However, we note that the total number of measures proposed for removal is 15 because the STK–4 and VTE–5 measures are being proposed for removal twice—once in the chart-abstracted form and again in electronic form.

The 13 eCQM versions of measures we are proposing to remove are: (1) AMI–2: Aspirin Prescribed at Discharge for AMI (NQF #0142); (2) AMI–7a: Fibrinolytic Therapy Received Within 30 minutes of Hospital Arrival; (3) AMI–10: Statin Prescribed at Discharge; (4) HTN: Healthy Term Newborn (NQF #0716); (5) PN–6: Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients (NQF #0147); (6) SCIP-Inf-1a: Prophylactic Antibiotic Received within 1 Hour Prior to Surgical Incision (NQF #0527); (7) SCIP-Inf-2a: Prophylactic Antibiotic Selection for Surgical Patients (NQF #0528); (8) SCIP Inf-9: Urinary Catheter Removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with Day of Surgery Being Day Zero; (9) STK–4: Thrombolytic Therapy (NQF #0437); (10) VTE–3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy (NQF #0373); (11) VTE–4: Venous Thromboembolism Patients Receiving Unfractionated Heparin (UFH) with Dosages/Platelet Count Monitoring by Protocol (or Nomogram); (12) VTE–5: Venous Thromboembolism Discharge Instructions; and (13) VTE–6: Incidence of Potentially Preventable Venous Thromboembolism.

The two chart-abstracted measures we are proposing to remove are: (1) STK–4: Thrombolytic Therapy (NQF #0437); and (2) VTE–5: Venous Thromboembolism Discharge Instructions. The two structural measures we are proposing to remove are: (1) Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care; and (2) Participation in a Systematic Clinical Database Registry for General Surgery.

We believe that removing 13 eCQMs will reduce burden for hospitals, as they would have a smaller number of eCQMs to select from. As finalized in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49698), hospitals are required to select 4 out of 28 available eCQMs on which to report data beginning with the FY 2018 payment determination. Since the measures proposed for removal are among the list of measures available, reducing the number of eCQMs from which hospitals choose would decrease the burden associated with selecting and reporting data for 4 eCQMs because hospitals would have only 15 eCQMs from which to select instead of 28 eCQMs. However, if our proposal to require hospitals to submit data on all of the available eCQMs included in the Hospital IQR Program measure set is finalized as proposed, this modest reduction in burden would be offset by the increased burden associated with submitting data on 15 eCQMs instead of 4 eCQMs. We discuss the burden associated with our proposal to require the submission of all available eCQMs included in the Hospital IQR Program measure set below.

We believe that there would be a reduction in burden for hospitals as a result of the removal of the two chart-abstracted measures listed above (STK–4 and VTE–5). Due to the burden associated with the collection of chart-abstracted data (based on updated measure record abstraction time estimates from the third quarter in 2014 through the second quarter in 2015 provided by CDAC, the number of reporting periods in a calendar year, and the number of IPPS hospitals reporting), we estimate that the removal of STK–4 would result in a burden reduction of approximately 303,534 hours and approximately $9.9 million across all 3,300 IPPS hospitals participating in the Hospital IQR Program for the FY 2019 payment determination. In addition, we estimate that the removal of VTE–5 would result in a burden reduction of approximately 653,565 hours and approximately $21.4 million across all 3,300 IPPS hospitals participating in the Hospital IQR Program for the FY 2019 payment determination. More specifically, for both the STK and VTE measure sets, we calculated the burden hours by taking the difference in the burden estimates from this FY 2017 IPPS/LTCH PPS proposed rule and the burden estimates from the FY 2016 IPPS/LTCH PPS final rule. With regard to STK–4, because it is the only STK measure left in the Hospital IQR Program, and we are proposing in this FY 2017 IPPS/LTCH PPS proposed rule to remove it, we calculated the total burden hours as follows: 0 hours (time required to report in CY 2017) − 303,534 hours (time required to report in CY 2016) = −303,534 hours for the STK measure set. With regard to the VTE measure set, we used an updated estimate from CDAC that the time per record (that is, to report all of the VTE measures in the Hospital IQR Program) is 28 minutes, and in the FY 2016 IPPS/LTCH PPS final rule, we estimated a burden reduction of 10 minutes for removing 3 VTE measures (or approximately 3 minutes per measure). As such, we deducted 3 minutes from the 28 minute estimate to account for the proposed removal of VTE–5, for a total of 25 minutes to report on the remaining VTE measure in the Hospital IQR Program. We then calculated the estimated total burden hours per hospital for reporting the remaining VTE measure as follows: 25 minutes per record/60 minutes per hour × 4 reporting quarters per year × 198.05 records per hospital per quarter = 330 burden hours per hospital. Because there are 3,300 IPPS hospitals, we then multiplied 330 hours per hospital × 3,300 hospitals to get a total annual burden estimate of 1,089,275 hours to report the remaining measure in the VTE measure set. To demonstrate the reduction in the total burden hours for VTE from this FY 2017 IPPS/LTCH PPS proposed rule and the FY 2016 IPPS/LTCH PPS final rule, we calculated as follows: 1,089,275 (FY 2017 total annual estimate) − 1,742,840 (FY 2016 total annual estimate) = −653,565 hours for the VTE measure set.

We believe that there will be a negligible burden reduction due to the removal of two structural measures. Consistent with previous years (80 FR 49762), we estimate a burden of 15 minutes per hospital to report all four previously finalized structural measures and to complete other forms (such as the Extraordinary Circumstances Extension/Exemption Request Form). Therefore, our burden estimate of 15 minutes per hospital remains unchanged because we believe the reduction in burden associated with removing these two structural measures will be sufficiently minimal that it will not substantially impact this estimate.

In addition, in section VIII.A.6. of the preamble of this proposed rule, we are proposing refinements to two previously adopted measures: (1) Expanding the cohort for the Hospital-Level, Risk-standardized Payment Associated with a 30-Day Episode-of-Care for Pneumonia (NQF #2579); and (2) adopting the modified Patient Safety and Adverse Events Composite (NQF #0531). Because these claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, we believe no additional burden on hospitals will result from the proposed refinements to these two claims-based measures.

Also, in section VIII.A.7. of the preamble of this proposed rule, we are proposing to add four claims-based measures to the Hospital IQR Program measure set beginning with the FY 2019 payment determination: (1) Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure; (2) Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure; (3) Spinal Fusion Clinical Episode-Based Payment Measure; and (4) Excess Days in Acute Care after Hospitalization for Pneumonia. Because these claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, we believe no additional burden on hospitals will result from the addition of these four proposed claims-based measures.

For the FY 2019 payment determination and subsequent years, in section VIII.A.8. of the preamble of this proposed rule, we also are proposing to require hospitals to submit data for all eCQMs included in the Hospital IQR Program measure set in a manner that will permit eligible hospitals to align Hospital IQR Program requirements with some requirements under the Medicare and Medicaid EHR Incentive Programs. Specifically, hospitals would be required to submit a full calendar year of data on all eCQMs in the Hospital IQR Program measure set, on an annual basis, beginning with CY 2017 reporting. We believe that the total burden associated with the eCQM reporting proposal would be similar to that previously outlined in the Medicare EHR Incentive Program Stage 2 final rule (77 FR 54126 through 54133). In that final rule, the burden estimate for a hospital to report all 16 eCQMs is 2 hours and 40 minutes (160 total minutes or 10 minutes per measure) per submission for a 3-month period (77 FR 54127). We believe that this estimate is accurate and appropriate to apply to the Hospital IQR Program because we are proposing to align the eCQM reporting requirements between both programs. As such, using the estimate of 10 minutes per measure, we anticipate that if our proposals to: (1) Require reporting on all of the available eCQMs (15 eCQMs for the CY 2017 reporting period/FY 2019 payment determination); and (2) submit one year of eCQM data (covering Q1, Q2, Q3, and Q4), both are finalized as proposed, it would take a hospital 150 minutes per quarter to report one medical record containing information on all the required eCQMs. In total, for the FY 2019 payment determination, we expect our proposal to require hospitals to report data on 15 eCQMs for 4 quarters (as compared to our previously finalized requirement to report data on 4 eCQMs for 1 quarter) would represent a burden increase of 30,800 hours across all 3,300 IPPS hospitals participating in the Hospital IQR Program. This figure was derived by calculating the difference between the FY 2017 burden estimate of 33,000 hours (150 minutes per record/60 minutes per hour × 4 reporting quarters per year × 1 record per hospital per quarter × 3,300 hospitals) and the FY 2016 burden estimate of 2,200 hours (20 minutes per record/60minutes per hour × 1 reporting quarter per year × 1 record per hospital per quarter × 3,300 hospitals) (80 FR 49763), for an incremental increase of 30,800 hours.

Furthermore, we estimate that reporting these eCQMs can be accomplished by staff with a mean hourly wage of $16.42 per hour.[316] However, obtaining data on other overhead costs is challenging. Overhead costs vary greatly across industries and firm sizes. In addition, the precise cost elements assigned as "indirect" or "overhead" costs, as opposed to direct costs or employee wages, are subject to some interpretation at the firm level. Therefore, we have chosen to calculate the cost of overhead at 100 percent of the mean hourly wage. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method. This is a change from how we have accounted for the cost of overhead in our previous rules regarding the Hospital IQR Program. In calculating labor cost, we estimate an hourly labor cost of $32.84 ($16.42 base salary + $16.42 fringe) and a cost increase of $1,011,472.00 (30,800 additional burden hours × $32.84 per hour) across approximately 3,300 hospitals participating in the Hospital IQR Program to report a full calendar year of data for 15 eCQMs, on an annual basis.

We are not proposing any changes to our validation requirements related to chart-abstracted measures, but are providing some background information as basis for our eCQM validation proposals. As noted in the FY 2016 IPPS/LTCH IPPS final rule (80 FR 49762 and 49763), for validation of chart-abstracted data for the FY 2018 payment determination and subsequent years, we require hospitals to provide 72 charts per hospital per year (with an average page length of 1,500), including 40 charts for HAI validation and 32 charts for clinical process of care validation, for a total of 108,000 pages per hospital per year. We reimburse hospitals at 12 cents per photocopied page (79 FR 50346) for a total per hospital cost of $12,960. For hospitals providing charts digitally via a re-writable disc, such as encrypted CD–ROMs, DVDs, or flash drives, we will reimburse hospitals at a rate of 40 cents per digital media (80 FR 49837), and additionally hospitals will be reimbursed $3.00 per record (78 FR 50956). For hospitals providing charts via secure file transfer, we will reimburse hospitals at a rate of $3.00 per record (78 FR 50835).

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[316] Occupational Outlook Handbook. Available at: *http://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.html.*

In section VIII.A.11. of the preamble of this proposed rule, beginning in spring 2018 for the FY 2020 payment determination, we are proposing to modify the existing validation process for the Hospital IQR Program data to include a random sample of up to 200 hospitals for validation of eCQMs in the Hospital IQR Program. In previous years (79 FR 50347), we estimated a total burden of 16 hours (960 minutes) for the submission of 12 records, which would equal 1 hour and 20 minutes per record (960 minutes/12 records). Applying the time per individual submission of 1 hour and 20 minutes (or 80 minutes) for the 32 records we are proposing hospitals submit beginning with the FY 2020 payment determination, we estimate a total burden of approximately 43 hours (1 hour and 20 minutes × 32 records) for each hospital selected for participation in eCQM validation. We estimate that approximately 43 hours of work for up to 200 hospitals would increase the eCQM validation burden hours from 0 hours (as this is the first instance where eCQM validation is being proposed as a requirement) to 8,533 labor hours.

As previously stated, with respect to eCQMs, the labor performed can be accomplished by staff, with a mean hourly wage of $16.42.[317] Further, in calculating labor costs, we have chosen to calculate the cost of overhead at 100 percent of the mean hourly wage. As such, we estimate a fully burdened labor rate of $32.84 ($16.42 base salary + $16.42 fringe) per hour. Therefore, using these assumptions, we estimate an hourly labor cost of $32.84 and a cost increase of $280,224 (8,533 additional burden hours × $32.84 per hour) across the (up to) 200 hospitals selected for eCQM validation, on an annual basis. Consistent with the chart-abstraction validation process, we will reimburse hospitals providing records via secure file transfer, at a rate of $3.00 per record.

Lastly, in section VIII.A.15. of the preamble of this proposed rule, we are proposing to update our Extraordinary Circumstances Extensions or Exemptions (ECE) policy by: (1) Extending the general ECE request deadline for non-eCQM circumstances from 30 to 90 calendar days following an extraordinary circumstance; and (2) establishing a separate submission deadline for ECE requests with respect to eCQM reporting circumstances of April 1 following the end of the reporting calendar year. Consistent with previous years, we estimate a burden of 15 minutes per hospital to report all forms (including the ECE request form) and structural measures. We believe that the proposed updates to the ECE deadlines will have no effect on burden for hospitals, because we are not making any changes that will increase the amount of time necessary to complete the form. In addition, the burden associated with the completion of this form is included in the 15 minutes allocated for all forms and structural measures.

In summary, under OMB number 0938–1022, we estimate a total burden decrease of approximately 917,766 hours, for a total cost decrease of approximately $30 million across approximately 3,300 hospitals participating in the Hospital IQR Program as a result of the policies proposed in this proposed rule.

The estimate excludes the burden associated with the NHSN and HCAHPS measures, both of which are submitted under separate information collection requests and are approved under OMB control numbers 0920–0666 and 0938–0981, respectively. The burden estimates in this proposed rule are the estimates for which we are requesting OMB approval.

7. ICRs for PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

As discussed in sections VIII.B. of the preamble of this proposed rule, section 1866(k)(1) of the Act requires, for purposes of FY 2014 and each subsequent fiscal year, that a hospital described in section 1886(d)(1)(B)(v) of the Act (a PPS-exempt cancer hospital, or a PCH) submit data in accordance with section 1866(k)(2) of the Act with respect to such fiscal year.

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 28124), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50957 through 50959), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50347 through 50348), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49764) for a detailed discussion of the burden for the program requirements that we have previously adopted. Below we discuss only any changes in burden that would result from the proposals in this proposed rule.

In section VIII.B.3.b. of the preamble of this proposed rule, we are proposing that PCHs submit data on Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382) measure for an expanded cohort of patients. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50285) we finalized a sampling methodology for Clinical Process/Oncology Care Measures, which includes the Oncology: Radiation Dose Limits to Normal Tissues measure. Because our previous burden estimates were based on the maximum sample for this measure, the expansion of the patient cohort would not raise the burden for this measure beyond that which we described in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50347 through 50348).

In section VIII.B.4.b. of the preamble of this proposed rule, we are proposing to adopt the Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy measure beginning with the FY 2019 program year. This is a claims-based measure, and therefore, does not require PCHs to submit any new data. Thus, this measure would not pose any new burden on PCHs.

In summary, as a result of our proposals, we do not anticipate any changes to previously finalized burden estimates.

8. ICRs for the Hospital Value-Based Purchasing (VBP) Program

In section IV.H. of the preamble of this proposed rule, we discuss proposed requirements for the Hospital VBP Program. Specifically, in this proposed rule, with respect to quality measures, we are proposing to: Include selected ward non-Intensive Care Unit (ICU) locations in certain NHSN measures beginning with the FY 2019 program year; adopt the Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI) and the Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Heart Failure (HF) measures for the FY 2021 program year; update the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia (PN) Hospitalization (Updated Cohort) measure for the FY 2021 program year; and adopt the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery measure for the FY 2022 program year.

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[317] Occupational Outlook Handbook. Available at: *http://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.html.*

As required under section 1886(o)(2)(A) of the Act, the additional and updated measures are required for the Hospital IQR Program. Therefore, their inclusion in the Hospital VBP Program does not result in any additional burden because the Hospital VBP Program uses data that are required for the Hospital IQR Program.

9. ICRs for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

As discussed in section VIII.C.5 of the preamble of this proposed rule, we are retaining the following 13 previously finalized quality measures for use in the LTCH QRP:

LTCH QRP QUALITY MEASURES PREVIOUSLY ADOPTED FOR THE FY 2014 PAYMENT DETERMINATIONS AND SUBSEQUENT YEARS

Measure title	IPPS/LTCH PPS final rule	Annual payment determination: Initial and subsequent APU years
National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138).	Adopted an application of the measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51745 through 51747); Adopted the NQF-endorsed version and expanded measure (with standardized infection ratio [SIR]) in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53616 through 53619)	FY 2014 payment determination and subsequent years.
National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139).	Adopted an application of the measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51747 through 51748); Adopted the NQF-endorsed and expanded measure (with SIR) in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53616 through 53619).	FY 2014 payment determination and subsequent years.
Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678).	Adopted an application of the measure in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51748 through 51750); Adopted the NQF-endorsed version in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50861 through 50863); Adopted in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49731 through 49736) to fulfill IMPACT Act requirements.	FY 2014 payment determination and subsequent years.
Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680).	Adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53624 through 53627); Revised data collection timeframe in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50858 through 50861); Revised data collection timeframe in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50289 through 50290).	FY 2016 payment determination and subsequent years.
Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431).	Adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53630 through 53631); Revised data collection timeframe in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50857 through 50858).	FY 2016 payment determination and subsequent years.
National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716).	Adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50863 through 50865).	FY 2017 payment determination and subsequent years.
National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717).	Adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50865 through 50868).	FY 2017 payment determination and subsequent years.
All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Long-Term Care Hospitals (NQF #2512).	Adopted in FY 2014 IPPS/LTCH PPS final rule (78 FR 50868 through 50874); Adopted the NQF-endorsed version in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49730 through 49731).	FY 2017 payment determination and subsequent years.
National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure.	Adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50301 through 50305).	FY 2018 payment determination and subsequent years.

LTCH QRP Quality Measures Previously Adopted for the FY 2014 Payment Determinations and Subsequent Years—Continued

Measure title	IPPS/LTCH PPS final rule	Annual payment determination: Initial and subsequent APU years
Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).	Adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50874 through 50877); Revised data collection timeframe in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50290 through 50291); Adopted an application of the measure in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49736 through 49739) to fulfill IMPACT Act requirements.	FY 2018 payment determination and subsequent years.
Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).	Adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50291 through 50298).	FY 2018 payment determination and subsequent years.
Functional Outcome Measure: Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632).	Adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50298 through 50301).	FY 2018 payment determination and subsequent years.
Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).	Adopted an application of the measure in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49739 through 49747) to fulfill IMPACT Act requirements.	FY 2018 payment determination and subsequent years.

As discussed in section VIII.C.6 and VIII.C.7 of the preamble of this proposed rule, we are proposing the following four measures for use in the LTCH QRP:

LTCH QRP Quality Measures Proposed for the FY 2018 Payment Determination and Subsequent Years

Measure title	Annual payment determination: Initial and subsequent APU years
Potentially Preventable 30-Day Post-Discharge Readmission Measure for the LTCH QRP*.	FY 2018 payment determination and subsequent years.
Discharge to Community-PAC LTCH QRP*	FY 2018 payment determination and subsequent years.
MSPB–PAC LTCH QRP*	FY 2018 payment determination and subsequent years.
Drug Regimen Review Conducted with Follow-Up for Identified Issues- PAC LTCH QRP**.	FY 2020 payment determination and subsequent years.

* Proposed in this FY 2017 IPPS/LTCH PPS proposed rule for the FY 2018 payment determination and subsequent years.
** Proposed in this FY 2017 IPPS/LTCH PPS proposed rule for the FY 2020 payment determination and subsequent years.

Currently, LTCHs use two separate data collection mechanisms to report quality data to CMS. Six of the 13 measures being retained in this FY 2017 IPPS/LTCH PPS proposed rule are currently collected via the CDC's NHSN. The NHSN is a secure, Internet-based HAI tracking system maintained and managed by the CDC. The NHSN enables health care facilities to collect and use data about HAIs, adherence to clinical practices known to prevent HAIs, and other adverse events within their organizations. NHSN data collection occurs via a Web-based tool hosted by the CDC and is provided free of charge to facilities. In this proposed rule, we are not proposing any new quality measures that would be collected via the CDC's NHSN. Therefore, at this time, there would be no additional burden related to this submission method. Any burden related to NHSN-based quality measures we have retained in this proposed rule has been previously discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50443 through 50445) and FY 2016 IPPS/LTCH PPS final rule (80 FR 49766) and has been previously approved under OMB control number 0920–0666, with an expiration date of November, 31, 2016.

In addition to the previously finalized All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge From LTCHs (NQF #2512), we are proposing three additional Medicare FFS claims-based measures in this proposed rule: Potentially Preventable 30 Day Post-Discharge Readmission Measure for LTCH QRP; Discharge to Community—PAC LTCH QRP; and MSBP–PAC LTCH QRP. Because these proposed claims-based measures would be calculated based on data that are already reported to the Medicare program for payment purposes, we believe no additional information collection would be required from the LTCHs. We are not proposing new assessment-based quality measures in the LTCH QRP in this proposed rule for the FY 2018 payment determination and subsequent years.

The remaining assessment-based quality measure data are reported to CMS by LTCHs using the LTCH CARE Data Set. In section VIII.C.9.d. of the preamble of this of this proposed rule, we are proposing to expand the data collection timeframe for the measure NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (77 FR 53624 through 53627), beginning with the FY 2019 payment determination. The data collection time frame and associated data submission deadlines are currently aligned with the Influenza Vaccination Season (IVS) (October 1 of a given year through March 31 of the subsequent year), and only require data collection during the 2 calendar year quarters that align with the IVS. We are proposing to expand the data collection timeframe from just 2 quarters (covering the IVS) to a full four quarters or 12 months. We refer readers to section VIII.C.9.d. of the preamble of this this proposed rule for further details on the proposed expansion of data collection for this measures (NQF #0680), including data collection timeframes and associated submission deadlines. We originally finalized this measure for use in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53624 through 53627). Although we finalized data collection for this measure to coincide with the IVS, we originally proposed year-round data collection. The associated PRA package, which was approved under OMB control number 0938–1163, included burden calculations that aligned with our original proposal for year-round data collection. All subsequent PRA packages, and the PRA package that is currently under review, included burden calculations reflecting year-round (12 month) data collection for this measure. Because of this, the proposed change in the data collection timeframe for this measure, and any associated burden related to increased data collection, has already been accounted for in the total burden figures included in this section of the preamble of this proposed rule.

For the FY 2020 payment determination and subsequent years, we are proposing the use of one new assessment based quality measure in the LTCH QRP: Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP. This is a cross-setting measure that satisfies the required addition of a quality measure under the domain of medication reconciliation, as mandated by section 1899B of the Act, as added by the IMPACT Act. In addition to the proposed Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP quality measure, the remaining six measures, outlined below, will continue to be collected utilizing the LTCH CARE Data Set.

The LTCH CARE Data Set Version 2.01 has been approved under OMB control number 0938–1163. The LTCH CARE Data Set Version 2.01 contains data elements related to patient demographic data, various voluntary questions, as well as data elements related to the following quality measures:

- Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678);
- Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680).

We have submitted a revision to the PRA package that addressed the changes from LTCH CARE Data Set Version 2.01 to Version 3.00. The LTCH CARE Data Set Version 3.00, which is to be implemented April 1, 2016, contains those data elements included in Version 2.01, as well as additional data elements in order to allow for the collection of data associated with the following quality measures:

- Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) (previously finalized in the FY 2016 IPPS/LTCH PPS final rule);
- Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631) (previously finalized in the FY 2015 IPPS/LTCH PPS final rule);
- Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632) (previously finalized in the FY 2015 IPPS/LTCH PPS final rule); and
- Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631) (previously finalized in the FY 2016 IPPS/LTCH PPS final rule).

The LTCH CARE Data Set Version 4.00, effective April 1, 2018, will contain those data elements included in Version 3.00, as well as additional data elements in order to allow for the collection of data associated with the proposed quality measure: Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC LTCH QRP, proposed in this proposed rule.

Each time we add new data elements to the LTCH CARE Data Set related to newly proposed or finalized LTCH QRP quality measures, we are required by the PRA to submit the expanded data collection instrument to OMB for review and approval. Section 1899B(m) of the Act, as added by IMPACT Act, provides that the PRA requirements do not apply to section 1899B of the Act and the sections referenced in section 1899B(a)(2)(B) of the Act that require modifications in order to achieve the standardization of patient assessment data. We believe that the LTCH CARE Data Set Version 3.00 falls under the PRA provisions in 1899B(m) of the Act. We believe that all additional data elements added to the LTCH CARE Data Set Version 3.00 are for the purpose of standardizing patient assessment data, as required under section 1899B(a)(2)(B) of the Act. As noted above, the LTCH CARE Data Set Version 3.00 would be updated to Version 4.0, effective April 1, 2018, to include data elements for the Drug Regimen Review Conducted with Follow-Up for Identified Issues- PAC LTCH QRP proposed quality measure, if the measure is finalized. For the reasons discussed above, we believe that the LTCH CARE Data Set Version 4.00 also falls under the PRA provisions in section 1899B(m) of the Act.

A comprehensive list of all data elements included in the LTCH CARE Data Set Version 3.00 is available in the LTCH QRP Manual which is accessible on the LTCH QRP Web site at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index.html.* For a discussion of burden related to LTCH CARE Data Set Version 3.00, we refer readers to section I.M. of Appendix A of this proposed rule.

10. ICRs for the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program

Section 1886(s)(4) of the Act, as added and amended by sections 3401(f) and 10322(a) of the Affordable Care Act, requires the Secretary to implement a quality reporting program for inpatient psychiatric hospitals and psychiatric units. We refer to this program as the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program.

In section VIII.D. of the preamble of this proposed rule, we are proposing the following measure-related changes: To update a previously finalized measure (Screening for Metabolic Disorders); and to adopt two new measures beginning with the FY 2019 payment determination (SUB–3 Alcohol & Other Drug Use Disorder Treatment Provided or Offered at Discharge and subset measure SUB–3a Alcohol & Other Drug Use Disorder Treatment at Discharge (NQF #1664), and Thirty-day all-cause unplanned readmission following psychiatric hospitalization in an IPF). We also are proposing to no longer specify in rulemaking when measure data will be publicly available, when the preview period will occur or that the preview period will begin approximately 12 weeks before the public display date, but rather to announce the timeframes using subregulatory guidance.

We refer readers to the FY 2015 IPF PPS final rule (79 FR 45978 through

45980) and the FY 2016 IPF PPS final rule (80 FR 46720 through 46721) for a detailed discussion of the burden for the IPFQR Program requirements that we have previously adopted. Below we discuss only the changes in burden resulting from the proposals in this proposed rule. Although we are proposing provisions that impact policies beginning in both the FY 2017 and FY 2019 payment determinations, IPFs must take steps to comply with all of these policies beginning in FY 2017. For example, data collection for the measures begins in FY 2017, and the changes to the public display dates take effect beginning in FY 2017. For purposes of calculating burden, we will attribute the costs to the year in which these costs begin; for the purposes of all of the proposals in this proposed rule, that year is FY 2017.

We believe that approximately 1,684 [318] IPFs will participate in the IPFQR Program for requirements occurring in FY 2017 and subsequent years. Based on program data, we believe that each IPF will submit measure data on approximately 848 [319] cases per year. In prior rulemaking, we estimated that the time required to chart-abstract data for chart-abstracted measures is 12 minutes per case per measure.[320] Based on the experience of other quality reporting programs, such as the Hospital IQR Program, we are updating this estimate to 15 minutes per case per measure. We are only proposing one chart-abstracted measure this year: SUB–3 and subset SUB–3a. The other measure that we are proposing, Thirty-day all-cause unplanned readmission following Psychiatric hospitalization in an IPF, is claims-based and, therefore, does not require IPFs to report any additional data.

We estimate that reporting data for the IPFQR Program measures can be accomplished by staff with a mean hourly wage of $16.42.[321] However, obtaining data on other overhead costs is challenging. Overhead costs vary greatly across industries and firm sizes. In addition, the precise cost elements assigned as "indirect" or "overhead" costs, as opposed to direct costs or employee wages, are subject to some interpretation at the firm level. Therefore, we have chosen to calculate the cost of overhead at 100 percent of the mean hourly wage. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method. In calculating the labor cost, we estimate an hourly labor cost of $32.84 ($16.42 base salary + $16.42 fringe). The following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefit (at 36.25% in $/hr)	Adjusted hourly wage ($/hr)
Medical Records and Health Information Technician	29–2071	16.42	16.42	32.84

We do not believe that our proposal to update a previously finalized measure will affect our previous burden estimate for that measure. As noted above, one of our proposed measures is claims-based and would not result in increased burden. Therefore, increased burden would occur primarily as a result of our proposed new chart-abstracted measure. We estimate that this proposal would result in an increase in burden of 212 hours per IPF (1 measure × (848 cases/measure × 0.25 hours/case)) or 357,008 hours across all IPFs (212 hours/IPF × 1,684 IPFs). The increase in costs would be approximately $6,962 per IPF (212 hours × $32.84/hour) or $11,724,143 across all IPFs (357,008 hours × 32.84/hour).

Consistent with our estimates in the FY 2015 IPF PPS final rule (79 FR 45979), we believe the estimated burden for training personnel on the revised data collection and submission requirements would be 2 hours per IPF or 3,368 hours (2 hours/IPF × 1,684 IPFs) across all IPFs. Therefore, we estimate the cost for this training would be $65.68 ($32.84/hour × 2 hours) for each IPF or $110,605 ($32.84/hour × 3,368 hours) for all IPFs.

Finally, IPFs must submit to CMS aggregate population counts for Medicare and non-Medicare discharges by age group and diagnostic group, and sample size counts for measures for which sampling is performed. Because the population for the SUB–3 and SUB–3a measure is nearly identical to the population for both the SUB–1 measure and the SUB–2 and SUB–2a measure, we believe that the addition of 1 chart-abstracted measure would lead to a negligible change in burden associated with nonmeasure data collection.

In section VIII.D.7. of the preamble of this proposed rule, we are proposing to no longer specify in rulemaking, but rather in subregulatory guidance, when measure data will be publicly available, when the preview period will occur, or that the preview period will begin approximately 12 weeks before the public display date. We do not believe this proposal will result in any change in burden because it does not require IPFs to report any more or less data. Rather, if finalized, the timeline for public display of that data is simply shifting.

In the table below, we set out a summary of annual burden estimates.

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[318] In the FY 2016 IPF PPS final rule, we estimated 1,617 IPFs and are adjusting that estimate by +67 to account for more recent data.

[319] In the FY 2016 IPF PPS final rule, we estimated 431 cases per year and are adjusting that estimate by +417 to account for more recent data.

[320] 80 FR 46720.

[321] *http://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.html.*

ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS UNDER OMB CONTROL NUMBER 0938–1171 (CMS–10432)

Proposed action [preamble section]	Respondents	Responses per respondent	Burden per response (hours) *	Total annual burden (hours)	Labor cost ($/hr)	Total cost ($)
Add NQF #1664 [VIII.D.4.a.]	1,684	848	0.25	357,008	32.84	11,724,143
Add Readmissions Measure [VIII.D.4.b.]	1,684	0	0	0	32.84	0
Training	1,684	1	2	3,368	32.84	110,605
Shift Public Display Timeline [VIII.D.7.]	1,684	0	0	0	32.84	0
	1,684	....	....	360,376	32.84	11,834,748

11. ICRs for the Electronic Health Record (EHR) Incentive Program and Meaningful Use

In section VIII.E. of the preamble of this proposed rule, we discuss our proposals to align the Medicare and Medicaid EHR Incentive Programs reporting and submission timelines for electronically submitted clinical quality measures for eligible hospitals and CAHs with the Hospital IQR Program's reporting and submission timelines for the FY 2019 payment determination. Because these proposals for data collection in this proposed rule will align with the reporting requirements in place for the Hospital IQR Program, and eligible hospitals and CAHs still have the option to submit their clinical quality measures via attestation for the Medicare and Medicaid EHR Incentive Programs for CY 2017 reporting, we do not believe there is any additional burden for this collection of information. However, starting with CY 2018 reporting, eligible hospitals and CAHs participating in the Medicare EHR Incentive Programs must electronically report CQMs using CEHRT where feasible; and attestation to CQMs will no longer be an option except in certain circumstances where electronic reporting is not feasible (80 FR 62894).

We are requesting public comments on these information collection and recordkeeping requirements.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, CMS–1655–P

Fax: (202) 395–6974; or

Email: OIRA_submission@omb.eop.gov.

C. Response to Public Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all public comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the public comments in the preamble of that document.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping, Rural areas, X-rays.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons stated in the preamble of this proposed rule, the Centers for Medicare & Medicaid Services is proposing to amend 42 CFR Chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: Secs. 205(a), 1102, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 2. Section 405.926 is amended by adding paragraph (u) to read as follows:

§ 405.926 Actions that are not initial determinations.

* * * * *

(u) Issuance of notice to an individual entitled to Medicare benefits under Title XVIII of the Act when such individual received observation services as an outpatient for more than 24 hours, as specified under § 489.20(y) of this chapter.

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 3. The authority citation for part 412 is revised to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), sec. 124 of Pub. L. 106–113 (113 Stat. 1501A–332), sec. 1206 of Pub. L. 113–67, and sec. 112 of Pub. L. 113–93.

■ 4. Section 412.64 is amended by adding paragraph (d)(1)(vii) and revising paragraphs (h)(4) introductory text and (h)(4)(vi) introductory text to read as follows:

§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

* * * * *

(d) * * *

(1) * * *

(vii) For fiscal year 2017, the percentage increase in the market basket index (as defined in § 413.40(a)(3) of this chapter) for prospective payment hospitals, subject to the provisions of paragraphs (d)(2) and (3) of this section, less a multifactor productivity adjustment (as determined by CMS) and less 0.75 percentage point.

* * * * *

(h) * * *

(4) For discharges on or after October 1, 2004 and before October 1, 2017, CMS establishes a minimum wage index for each all-urban State, as defined in paragraph (h)(5) of this section. This minimum wage index value is computed using the following methodology:

* * * * *

(vi) For discharges on or after October 1, 2012 and before October 1, 2017, the minimum wage index value for the State is the higher of the value determined under paragraph (h)(4)(iv) of this section or the value computed using the following alternative methodology:

* * * * *

■ 5. Section 412.103 is amended by adding paragraph (b)(6) to read as follows:

§ 412.103 Special treatment: Hospitals located in urban areas and that apply for reclassification as rural.

* * * * *

(b) * * *

(6) *Lock-in date for the wage index calculation and budget neutrality.* In order for a hospital to be treated as rural in the wage index and budget neutrality calculations under §§ 412.64(e)(1)(ii), (e)(2) and (4), and (h) for the payment rates for the next Federal fiscal year, the hospital's filing date must be no later than 70 days prior to the second Monday in June of the current Federal fiscal year and the application must be approved by the CMS Regional Office in accordance with the requirements of this section.

* * * * *

■ 6. Section 412.106 is amended by revising paragraph (g)(1)(iii)(C) to read as follows:

§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * * *

(g) * * *

(1) * * *

(iii) * * *

(C)(*1*) For fiscal years 2014 and 2015, CMS will base its estimates of the amount of hospital uncompensated care on the most recent available data on utilization for Medicaid and Medicare SSI patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (b)(4) of this section.

(*2*) For fiscal year 2016, CMS will base its estimates of the amount of hospital uncompensated care on utilization data for Medicaid and Medicare SSI patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (b)(4) of this section, using data on Medicaid utilization from 2012 or 2011 cost reports from the most recent HCRIS database extract, the 2012 cost report data submitted to CMS by IHS hospitals, and the most recent available data on Medicare SSI utilization.

(*3*) For fiscal year 2017, CMS will base its estimates of the amount of hospital uncompensated care on utilization data for Medicaid and Medicare SSI patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (b)(4) of this section, using data on Medicaid utilization from 2011, 2012, and 2013 cost reports from the most recent HCRIS database extract, the 2011 and 2012 cost report data submitted to CMS by IHS hospitals, and the most recent available 3 years of data on Medicare SSI utilization (or, for Puerto Rico hospitals, a proxy for Medicare SSI utilization data).

(*4*) For fiscal year 2018, CMS will base its estimates of the amount of hospital uncompensated care determined in part from utilization data for Medicaid and Medicare SSI patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (b)(4) of this section, using data on Medicaid utilization from 2012 and 2013 cost reports from the most recent HCRIS database extract, the 2012 cost report data submitted to CMS by IHS hospitals, and the most recent available 2 years of data on Medicare SSI utilization (or, for Puerto Rico hospitals, a proxy for Medicare SSI utilization data), and determined in part on uncompensated care costs, defined as charity care costs plus non-Medicare bad debt costs, from 2014 cost reports also from the most recent HCRIS database extract.

(*5*) For fiscal year 2019, CMS will base its estimates of the amount of hospital uncompensated care determined in part from utilization data for Medicaid and Medicare SSI patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (b)(4) of this section, using data on Medicaid utilization from 2013 cost reports from the most recent HCRIS database extract and the most recent available year of data on Medicare SSI utilization (or, for Puerto Rico hospitals, a proxy for Medicare utilization data), and determined in part on uncompensated care costs, defined as charity care costs plus non-Medicare bad debt costs, from 2014 and 2015 cost reports also from the most recent HCRIS database extract.

(*6*) For fiscal year 2020, CMS will base its estimates of the amount of hospital uncompensated care on uncompensated care costs, defined as charity care costs plus non-Medicare bad debt costs, from 2014, 2015, and 2016 cost reports from the most recent HCRIS database extract.

(*7*) For fiscal years 2021 and subsequent years, CMS will base its estimates of the amount of hospital uncompensated care on uncompensated care costs, defined as charity care costs plus non-Medicare bad debt costs, using three cost reporting periods from the most recently available HCRIS database extract. For each fiscal year, the cost reporting periods will be advanced forward by one year (for example, for FY 2021, FYs 2016, 2017, and 2018 cost reports will be used).

* * * * *

■ 7. Section 412.140 is amended by revising paragraph (d)(2) to read as follows:

§ 412.140 Participation, data submission, and validation requirements under the Hospital Inpatient Quality Reporting (IQR) Program.

* * * * *

(d) * * *

(2) A hospital meets the chart-abstracted validation requirement with respect to a fiscal year if it achieves a 75-percent score, as determined by CMS.

* * * * *

■ 8. Section 412.160 is amended by revising the definitions of "Achievement threshold (or achievement performance standard)", "Benchmark", and "Cited for deficiencies that pose immediate jeopardy" to read as follows:

§ 412.160 Definitions for the Hospital Value-Based Purchasing (VBP) Program.

* * * * *

Achievement threshold (or achievement performance standard) means the median (50th percentile) of hospital performance on a measure during a baseline period with respect to a fiscal year, for Hospital VBP Program measures other than the measures in the Efficiency and Cost Reduction domain, and the median (50th percentile) of hospital performance on a measure during the performance period with respect to a fiscal year, for the measures in the Efficiency and Cost Reduction domain.

* * * * *

Benchmark means the arithmetic mean of the top decile of hospital performance on a measure during the baseline period with respect to a fiscal year, for Hospital VBP Program measures other than the measures in the Efficiency and Cost Reduction domain, and the arithmetic mean of the top decile of hospital performance on a measure during the performance period with respect to a fiscal year, for the measures in the Efficiency and Cost Reduction domain.

Cited for deficiencies that pose immediate jeopardy means that, during the applicable performance period, the Secretary cited the hospital for immediate jeopardy on at least three surveys using the Form CMS–2567, Statement of Deficiencies and Plan of Correction. CMS assigns an immediate jeopardy citation to a performance period as follows:

(1) If the Form CMS–2567 only contains one or more EMTALA-related immediate jeopardy citations, CMS uses the date that the Form CMS–2567 is issued to the hospital;

(2) If the Form CMS–2567 only contains one or more Medicare conditions of participation immediate jeopardy citations, CMS uses the survey end date generated in ASPEN; and

(3) If the Form CMS–2567 contains both one or more EMTALA-related immediate jeopardy citations and one or more Medicare conditions of participation immediate jeopardy citations, CMS uses the survey end date generated in ASPEN.

* * * * *

■ 9. Section 412.170 is amended by revising the definition of "Applicable period" to read as follows:

§ 412.170 Definitions for the Hospital-Acquired Condition Reduction Program.

* * * * *

Applicable period is, unless otherwise specified by the Secretary, with respect to a fiscal year, the 2-year period (specified by the Secretary) from which data are collected in order to calculate the total hospital-acquired condition score under the Hospital-Acquired Condition Reduction Program.

* * * * *

■ 10. Section 412.204 is amended by revising paragraph (d) introductory text and adding paragraph (e) to read as follows:

§ 412.204 Payment to hospitals located in Puerto Rico.

* * * * *

(d) *FY 2005 through December 31, 2015.* For discharges occurring on or after October 1, 2004 and before January 1, 2016, payments for inpatient operating costs to hospitals located in Puerto Rico that are paid under the prospective payment system are equal to the sum of—

* * * * *

(e) *January 1, 2016 and thereafter.* For discharges occurring on or after January 1, 2016, payments for inpatient operating costs to hospitals located in Puerto Rico that are paid under the prospective payment system are equal to 100 percent of a national prospective payment rate for inpatient operating costs, as determined under § 412.212.

■ 11. Section 412.256 is amended by revising paragraph (a)(1) to read as follows:

§ 412.256 Application requirements.

(a) * * *

(1) An application must be submitted to the MGCRB according to the method prescribed by the MGCRB, with an electronic copy of the application sent to CMS.

* * * * *

■ 12. Section 412.374 is amended by revising paragraph (b) introductory text and adding paragraph (e) to read as follows:

§ 412.374 Payments to hospitals located in Puerto Rico.

* * * * *

(b) *FY 2005 through FY 2016.* For discharges occurring on or after October 1, 2004 and on or before September 30, 2016, payments for capital-related costs to hospitals located in Puerto Rico that are paid under the prospective payment system are equal to the sum of the following:

* * * * *

(e) *FY 2016 and FYs thereafter.* For discharges occurring on or after October 1, 2016, payments for capital-related costs to hospitals located in Puerto Rico that are paid under the prospective payment system are based on 100 percent of the Federal rate, as determined under § 412.308.

■ 13. Section 412.503 is amended by adding in alphabetical order definitions of "MSA", "MSA-dominant area", and "MSA-dominant hospital" and revising the definitions of "Outlier payment" and "Subsection (d) hospital" to read as follows:

§ 412.503 Definitions.

* * * * *

MSA means a Metropolitan Statistical Area, as defined by the Executive Office of Management and Budget.

MSA-dominant area means an MSA in which an MSA-dominant hospital is located.

MSA-dominant hospital means a hospital that has discharged more than 25 percent of the total hospital Medicare discharges in the MSA (subject to the provisions of § 412.538(d)(2)(ii)) in which such subsection (d) hospital is located.

* * * * *

Outlier payment means an additional payment beyond the long-term care hospital standard Federal payment rate or the site neutral payment rate (including, when applicable, the blended payment rate), as applicable, for cases with unusually high costs.

* * * * *

Subsection (d) hospital means, for purposes of § 412.522, a hospital defined in section 1886(d)(1)(B) of the Social Security Act and includes any hospital that is located in Puerto Rico and that would be a subsection (d) hospital as defined in section 1886(d)(1)(B) of the Social Security Act if it were located in one of the 50 States.

* * * * *

■ 14. Section 412.507 is amended by revising paragraph (a) and adding paragraph (b)(3) to read as follows:

§ 412.507 Limitation on charges to beneficiaries.

(a) *Prohibited charges.* Except as provided in paragraph (b) of this section, a long-term care hospital may not charge a beneficiary for any covered services for which payment is made by Medicare, even if the hospital's costs of furnishing services to that beneficiary are greater than the amount the hospital is paid under the prospective payment system.

(1) If Medicare has paid at the full LTCH prospective payment system standard Federal payment rate, that payment applies to the hospital's costs for services furnished until the high-cost outlier threshold is met.

(2) If Medicare pays less than the full LTCH prospective payment system standard Federal payment rate and payment was not made at the site neutral payment rate (including, when applicable, the blended payment rate), that payment only applies to the hospital's costs for those costs or days used to calculate the Medicare payment.

(3) For cost reporting periods beginning on or after October 1, 2016, for Medicare payments to a long-term care hospital described in § 412.23(e)(2)(ii), that payment only applies to the hospital's costs for those costs or days used to calculate the Medicare payment.

(4) If Medicare has paid at the full site neutral payment rate, that payment applies to the hospital's costs for services furnished until the high-cost outlier is met.

(b) * * *

(3) For cost reporting periods beginning on or after October 1, 2016, a long-term care hospital described in § 412.23(e)(2)(ii) may only charge the Medicare beneficiary for the applicable deductible and coinsurance amounts under §§ 409.82, 409.83, and 409.87 of this chapter, for items and services as specified under § 489.20(a) of this chapter, and for services provided during the stay for which benefit days were not available and that were not the basis for adjusted LTCH prospective payment system payment amount under § 412.526.

■ 15. Section 412.522 is amended by adding paragraph (c)(2)(v) to read as follows:

§ 412.522 Application of site neutral payment rate.

* * * * *

(c) * * *

(2) * * *

(v) The limitation on long-term care hospital admissions from referring hospitals specified in § 412.538.

* * * * *

■ 16. Section 412.523 is amended by adding paragraph (c)(3)(xiii) to read as follows:

§ 412.523 Methodology for calculating the Federal prospective payment rates.

* * * * *

(c) * * *

(3) * * *

(xiii) *For long-term care hospital prospective payment system fiscal year beginning October 1, 2016, and ending September 30, 2017.* The LTCH PPS standard Federal payment rate for the long-term care hospital prospective payment system beginning October 1, 2016, and ending September 30, 2017, is the standard Federal payment rate for the previous long-term care hospital prospective payment system fiscal year updated by 1.45 percent and further adjusted, as appropriate, as described in paragraph (d) of this section.

* * * * *

■ 17. Section 412.525 is amended by adding paragraph (d)(6) to read as follows:

§ 412.525 Adjustments to the Federal prospective payment.

* * * * *

(d) * * *

(6) The limitation on long-term care hospital admissions from referring hospitals specified in § 412.538.

■ 18. The section heading of § 412.534 is revised to read as follows:

§ 412.534 Special payment provisions for long-term care hospitals-within-hospitals and satellites of long-term care hospitals, effective for discharges occurring on or before September 30, 2016.

* * * * *

■ 19. The section heading of § 412.536 is revised to read as follows:

§ 412.536 Special payment provisions for long-term care hospitals and satellites of long-term care hospitals that discharge Medicare patients admitted from a hospital not located in the same building or on the same campus as the long-term care hospital or satellite of the long-term care hospital, effective for discharges occurring on or before September 30, 2016.

* * * * *

■ 20. Add § 412.538 to read as follows:

§ 412.538 Limitation on long-term care hospital admissions from referring hospitals.

(a) *Scope.* (1) The provisions of this section apply to all long-term care hospitals excluded from the hospital inpatient prospective payment system under § 412.23(e), effective for discharges occurring on or after October 1, 2016, except as specified in paragraphs (a)(2) and (3) of this section.

(2) The provisions of this section do not apply to a long-term care hospital described in § 412.23(e)(2)(ii).

(3) The provisions of this section do not apply to a long-term care hospital described in § 412.23(e)(2)(i) that meets the criteria in § 412.22(f).

(b) *Discharges at or below the applicable percent threshold.* For any cost reporting period which includes discharges occurring on or after October 1, 2016, in which a long-term care hospital has a population of Medicare discharges occurring on or after October 1, 2016 of whom no more than the applicable percent threshold were admitted to the long-term care hospital from a single referring hospital as identified by the CCN, payments are made under the rules at §§ 412.500 through 412.541 with no adjustment under this section.

(c) *Discharges in excess of the applicable percent threshold.* For any cost reporting period which includes discharges occurring on or after October 1, 2016, in which a long-term care hospital has a population of Medicare discharges occurring on or after October 1, 2016 of whom more than the applicable percentage threshold (as defined in paragraph (e) of this section) were admitted to the long-term care hospital from a single referring hospital as identified by the CNN, payments for the Medicare discharges who are admitted from that referring hospital and who cause the long-term care hospital to exceed the applicable percentage threshold (as defined in paragraph (e) of this section) are to be paid at the lesser of the amount otherwise payable under this subpart or the amount equivalent to the hospital inpatient prospective payment system amount as defined in paragraph (f) of this section. Payments for discharges not in excess of the applicable percentage threshold (as defined in paragraph (e) of this section) are made under the rules at §§ 412.500 through 412.541 with no adjustment under this section.

(d) *Determination of exceeding the applicable percentage threshold.*—(1) *General.* The determination of whether a long-term care hospital has exceeded its applicable percentage threshold (as defined in paragraph (e) of this section) in regard to admissions from a single referring hospital as identified by the CNN is made by comparing the hospital's percentage of Medicare discharges occurring on or after October 1, 2016 admitted to the long-term care hospital (as calculated under paragraph (d)(2) of this section) to the long-term care hospital's applicable percentage threshold in paragraph (e) of this section.

(2) *Percentage of Medicare discharges.* For each individual referring hospital, the percentage of Medicare discharges admitted to the long-term care hospital is calculated by dividing the amount in paragraph (d)(2)(i) of this section by the amount in paragraph (d)(2)(ii) of this paragraph.

(i) The number of the long-term care hospital's Medicare discharges in the cost reporting period that were admitted from a single referring hospital as identified by the CNN on whose behalf an outlier payment was not made to that hospital and for whom payment was not made by a Medicare Advantage plan.

(ii) The long-term care hospital's total number of Medicare discharges in the long-term care hospital's cost reporting period for whom payment was not made by a Medicare Advantage plan.

(e) *Applicable percentage threshold*—(1) *General.* For the purposes of this section, except as provided for in paragraphs (f)(2) and (3) of this section, "applicable percentage threshold" means 25 percent.

(2) *Special treatment of exclusively rural long-term care hospitals.* In the case of a long-term care hospital that is located in a rural area as defined in § 412.503, the applicable percentage threshold means 50 percent. If an LTCH has multiple locations, all locations of the LTCH must be in a rural area (as defined in § 412.503) in order to be treated as rural under this section.

(3) *Special treatment for long-term care hospitals located in an MSA with an MSA-dominant hospital.* In the case of a long-term care hospital that admits Medicare patients from a referring MSA-dominant hospital (as defined in paragraph (h)(3)(ii) of this section), the applicable percentage threshold means the percentage of total subsection (d) hospital Medicare discharges in the MSA in which the long-term care hospital is located for the cost reporting period for which the adjustment under this section is made, but in no case is less than 25 percent or more than 50 percent. The determination of the applicable percentage threshold in this paragraph is subject to the provisions of paragraph (d)(2) of this section. If an LTCH has multiple locations payable

under this subpart, all locations of the LTCH must be in an MSA with an MSA-dominant hospital in order to be treated as such under this section.

(f) *Determining the amount equivalent to the hospital inpatient prospective payment system amount.* (1) As specified in paragraphs (b) and (c) of this section, CMS calculates an amount payable under subpart O that is equivalent to an amount that would be paid for the services provided if such services had been provided in an inpatient prospective payment system hospital (that is, the amount that would be determined under the rules at § 412.1(a)). This amount is based on the sum of the applicable hospital inpatient prospective payment system operating standardized amount and capital Federal rate in effect (as set forth in section § 412.529(d)(4)) at the time of the long-term care hospital discharge.

(2) In addition to the payment amount under paragraph (f)(1) of this section, an additional payment for high-cost outlier cases is based on the applicable fixed-loss amount established for the hospital inpatient prospective payment system in effect at the time of the long-term care hospital discharge.

■ 21. Section 412.560 is amended by revising paragraph (c)(1) to read as follows:

§ 412.560 Participation, data submission, and other requirements under the Long-Term Care Hospital Quality Reporting (LTCHQR) Program.

* * * * *

(c) * * *

(1) A long-term care hospital that wishes to request an exception or extension with respect to quality data reporting requirements must submit its request to CMS within 90 days of the date that the extraordinary circumstances occurred.

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END–STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ 22. The authority for part 413 is revised to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883 and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Pub. L. 106–113 (113 Stat. 1501A–332), sec. 3201 of Pub. L. 112–96 (126 Stat. 156), sec. 632 of Pub. L. 112–240 (126 Stat. 2354), sec. 217 of Pub. L. 113–93 (129 Stat. 1040), and sec. 204 of Pub L. 113–295 (128 Stat. 4010).

■ 23. Section 413.17 is amended by revising paragraph (d)(1) introductory text to read as follows:

§ 413.17 Cost to related organizations.

* * * * *

(d) * * *

(1) An exception is provided to this general principle if the provider demonstrates by convincing evidence to the satisfaction of the contractor, that—

* * * * *

■ 24. Section 413.24 is amended by revising paragraphs (f)(4)(i), (ii), and (iv) to read as follows:

§ 413.24 Adequate cost data and cost finding.

* * * * *

(f) * * *

(4) * * *

(i) As used in this paragraph, "provider" means a hospital, skilled nursing facility, home health agency, hospice, organ procurement organization, histocompatibility laboratory, rural health clinic, Federally qualified health center, community mental health center, or end-stage renal disease facility.

(ii) Effective for cost reporting periods beginning on or after October 1, 1989 for hospitals, cost reporting periods ending on or after February 1, 1997 for skilled nursing facilities and home health agencies, cost reporting periods ending on or after December 31, 2004 for hospices, and end-stage renal disease facilities, and cost reporting periods ending on or after March 31, 2005 for organ procurement organizations, histocompatibility laboratories, rural health clinics, Federally qualified health centers, and community mental health centers, a provider is required to submit cost reports in a standardized electronic format. The provider's electronic program must be capable of producing the CMS standardized output file in a form that can be read by the contractor's automated system. This electronic file, which must contain the input data required to complete the cost report and to pass specified edits, must be forwarded to the contractor for processing through its system.

* * * * *

(iv) Effective for cost reporting periods ending on or after September 30, 1994 for hospitals, cost reporting periods ending on or after February 1, 1997 for skilled nursing facilities and home health agencies, cost reporting periods ending on or after December 31, 2004 for hospices and end-stage renal disease facilities, and cost reporting periods ending on or after March 31, 2005 for organ procurement organizations, histocompatibility laboratories, rural health clinics, Federally qualified health centers, and community mental health centers, a provider must submit a hard copy of a settlement summary, a statement of certain worksheet totals found within the electronic file, and a statement signed by its administrator or chief financial officer certifying the accuracy of the electronic file or the manually prepared cost report. During a transition period (first two cost-reporting periods on or after December 31, 2004 for hospices and end-stage renal disease facilities, and the first two cost-reporting periods on or after March 31, 2005 for organ procurement organizations, histocompatibility laboratories, rural health clinics, Federally qualified health centers, community mental health centers), providers must submit a hard copy of the completed cost report forms in addition to the electronic file. The following statement must immediately precede the dated signature of the provider's administrator or chief financial officer:

I hereby certify that I have read the above certification statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by ______(Provider Name(s) and Number(s)) for the cost reporting period beginning ___and ending ___and that to the best of my knowledge and belief, this report and statement are true, correct, complete and prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

* * * * *

■ 25. Section 413.79 is amended by revising paragraphs (k)(1)(i) and (ii), (k)(2)(i) and (ii), (k)(3) and (4), and (k)(7)(ii) and (iii) to read as follows:

§ 413.79 Direct GME payments: Determination of the weighted number of FTE residents.

* * * * *

(k) * * *

(1) * * *

(i) For rural track programs started prior to October 1, 2012, for the first 3 years of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of

FTE residents, subject to the rolling average at paragraph (d)(7) of this section, training in the rural track at the urban hospital. For rural track programs started on or after October 1, 2012, prior to the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average at paragraph (d)(7) of this section, training in the rural track at the urban hospital.

(ii) For rural track programs started prior to October 1, 2012, beginning with the fourth year of the rural track's existence, the rural track FTE limitation is equal to the product of the highest number of residents, in any program year, who during the third year of the rural track's existence are training in the rural track at the urban hospital or the rural hospital(s) and are designated at the beginning of their training to be rotated to the rural hospital(s) for at least two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2002, or for more than one-half of the duration of the program effective for cost reporting periods beginning on or after October 1, 2003, and the number of years those residents are training at the urban hospital. For rural track programs started on or after October 1, 2012, beginning with the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation is equal to the product of the highest number of residents, in any program year, who during the fifth year of the rural track's existence are training in the rural track at the urban hospital or the rural hospital(s) and are designated at the beginning of their training to be rotated to the rural hospital(s) for more than one-half of the duration of the program, and the number of years those residents are training at the urban hospital.

(2) * * *

(i) For rural track programs started prior to October 1, 2012, for the first 3 years of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the urban hospital and the rural nonhospital site(s). For rural track programs started on or after October 1, 2012, prior to the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the urban hospital and the rural nonhospital site(s).

(ii)(A) For rural track programs started prior to October 1, 2012, beginning with the fourth year of the rural track's existence, the rural track FTE limitation is equal to the product of—

(*1*) The highest number of residents in any program year who, during the third year of the rural track's existence, are training in the rural track at—

(*i*) The urban hospital and are designated at the beginning of their training to be rotated to a rural nonhospital site(s) for at least two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000 and before October 1, 2003, or for more than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003; and

(*ii*) The rural nonhospital site(s); and

(*2*) The number of years in which the residents are expected to complete each program based on the minimum accredited length for the type of program.

(B) For rural track programs started on or after to October 1, 2012, beginning with the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation is equal to the product of—

(*1*) The highest number of residents in any program year who, during the fifth year of the rural track's existence, are training in the rural track at—

(*i*) The urban hospital and are designated at the beginning of their training to be rotated to a rural nonhospital site(s) for more than one-half of the duration of the program; and

(*ii*) The rural nonhospital site(s); and

(*2*) The number of years in which the residents are expected to complete each program based on the minimum accredited length for the type of program.

(3) For rural track programs started prior to October 1, 2012, if an urban hospital rotates residents in the rural track program to a rural hospital(s) for less than two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for one-half or less than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, the rural hospital may not include those residents in its FTE count (if the rural track is not a new program under paragraph (e)(3) of this section, or if the rural hospital's FTE count exceeds that hospital's FTE cap), nor may the urban hospital include those residents when calculating its rural track FTE limitation. For rural track programs started on or after October 1, 2012, if an urban hospital rotates residents in the rural track program to a rural hospital(s) for one-half or less than one-half of the duration of the program, the rural hospital may not include those residents in its FTE count (if the rural track is not a new program under paragraph (e)(3) of this section, or if the rural hospital's FTE count exceeds that hospital's FTE cap), nor may the urban hospital include those residents when calculating its rural track FTE limitation.

(4)(i) For rural track programs started prior to October 1, 2012, if an urban hospital rotates residents in the rural track program to a rural nonhospital site(s) for less than two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000 and before October 1, 2003, or for one-half or less than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, the urban hospital may include those residents in its FTE count, subject to the requirements under § 413.78(d). The urban hospital may include in its FTE count those residents in the rural track, not to exceed its rural track limitation, determined as follows:

(A) For the first 3 years of the rural track's existence, the rural track FTE limitation for the urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the rural nonhospital site(s).

(B) Beginning with the fourth year of the rural track's existence, the rural track FTE limitation is equal to the product of—

(*1*) The highest number of residents in any program year who, during the third year of the rural track's existence, are training in the rural track at the rural nonhospital site(s) or are designated at the beginning of their training to be rotated to the rural nonhospital site(s) for a period that is less than two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2002, and before October 1, 2003, or for one-half or less than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003; and

(*2*) The length of time in which the residents are training at the rural nonhospital site(s) only.

(ii) For rural track programs started on or after October 1, 2012, if an urban hospital rotates residents in the rural track program to a rural nonhospital site(s) for one-half or less than one-half of the duration of the program, the urban hospital may include those residents in its FTE count, subject to the requirements under § 413.78(d). The urban hospital may include in its FTE count those residents in the rural track, not to exceed its rural track limitation, determined as follows:

(A) Prior to the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation for the urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(*7*) of this section, training in the rural track at the rural nonhospital site(s).

(B) Beginning with the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation is equal to the product of—

(*1*) The highest number of residents in any program year who, during the fifth year of the rural track's existence, are training in the rural track at the rural nonhospital site(s) or are designated at the beginning of their training to be rotated to the rural nonhospital site(s) for a period that is for one-half or less than one-half of the duration of the program; and

(*2*) The length of time in which the residents are training at the rural nonhospital site(s) only.

* * * * *

(*7*) * * *

(ii)(A) For rural track programs started prior to October 1, 2012, effective October 1, 2014, if an urban hospital started a rural track training program under the provisions of this paragraph (k) with a hospital located in a rural area and, during the 3-year period that is used to calculate the urban hospital's rural track FTE limit, that rural area subsequently becomes an urban area due to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) and subject to paragraph (k)(*7*)(iii) of this section for the rural track programs started prior to the adoption of such new OMB standards for delineating statistical areas.

(B) For rural track programs started on or after October 1, 2012, effective October 1, 2014, if an urban hospital started a rural track training program under the provisions of this paragraph (k) with a hospital located in a rural area and, during the 5-year period that is used to calculate the urban hospital's rural track FTE limit, that rural area subsequently becomes an urban area due to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) and subject to paragraph (k)(*7*)(iii) of this section for the rural track programs started prior to the adoption of such new OMB standards for delineating statistical areas.

(iii)(A) For rural track programs started prior to October 1, 2012, effective October 1, 2014, if an urban hospital started a rural track training program under the provisions of this paragraph (k) with a hospital located in a rural area and that rural area subsequently becomes an urban area due to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, regardless of whether the redesignation of the rural hospital occurs during the 3-year period that is used to calculate the urban hospital's rural track FTE limit, or after the 3-year period used to calculate the urban hospital's rural track FTE limit, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) based on the rural track programs started prior to the change in the hospital's geographic designation. In order for the urban hospital to receive or use the adjustment to its FTE resident cap for training FTE residents in the rural track residency program that was started prior to the most recent OMB standards for delineating statistical areas adopted by CMS, one of the following two conditions must be met by the end of a period that begins when the most recent OMB standards for delineating statistical areas are adopted by CMS and continues through the end of the second residency training year following the date the most recent OMB delineations are adopted by CMS: the hospital that has been redesignated from rural to urban must reclassify as rural under § 412.103 of this chapter, for purposes of IME only; or the urban hospital must find a new site that is geographically rural consistent with the most recent geographical location delineations adopted by CMS. In order to receive an adjustment to its FTE resident cap for an additional new rural track residency program, the urban hospital must participate in a rural track program with sites that are geographically rural based on the most recent geographical location delineations adopted by CMS.

(B) For rural track programs started on or after October 1, 2012, effective October 1, 2014, if an urban hospital started a rural track training program under the provisions of this paragraph (k) with a hospital located in a rural area and that rural area subsequently becomes an urban area due to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, regardless of whether the redesignation of the rural hospital occurs during the 5-year period that is used to calculate the urban hospital's rural track FTE limit, or after the 5-year period used to calculate the urban hospital's rural track FTE limit, the urban hospital may continue to adjust its FTE resident limit in accordance with this paragraph (k) based on the rural track programs started prior to the change in the hospital's geographic designation. In order for the urban hospital to receive or use the adjustment to its FTE resident cap for training FTE residents in the rural track residency program that was started prior to the most recent OMB standards for delineating statistical areas adopted by CMS, one of the following two conditions must be met by the end of a period that begins when the most recent OMB standards for delineating statistical areas are adopted by CMS and continues through the end of the second residency training year following the date the most recent OMB delineations are adopted by CMS: The hospital that has been redesignated from rural to urban must reclassify as rural under § 412.103 of this chapter, for purposes of IME only; or the urban hospital must find a new site that is geographically rural consistent with the most recent geographical location delineations adopted by CMS. In order to receive an adjustment to its FTE resident cap for an additional new rural track residency program, the urban hospital must participate in a rural track program with sites that are geographically rural based on the most recent geographical location delineations adopted by CMS.

* * * * *

§ 413.200 [Amended]

■ 26. In § 413.200, paragraph (c)(1)(i), remove the phrase "three months" and add in its place the phrase "5 months".

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 27. The authority citation for part 489 is revised to read as follows:

Authority: Secs. 1102 1819, 1820(E), 1861, 1864(M), 1866, 1869, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395(hh)).

■ 28. Section 489.20 is amended by adding paragraph (y) to read as follows:

§ 489.20 Basic commitments.

* * * * *

(y) In the case of a hospital or critical access hospital, to provide notice, as specified in paragraphs (y)(1) and (2) of this section, to each individual entitled to Medicare benefits under Title XVIII of the Act when such individual receives observation services as an outpatient for more than 24 hours. Notice must be provided to the individual not later than 36 hours after observation services are initiated or sooner if the individual is transferred, discharged, or admitted.

(1) *Written notice.* Hospitals and critical access hospitals must use a standardized written notice, as specified by the Secretary, which includes the following information:

(i) An explanation of the status of the individual as an outpatient receiving observation services and not as an inpatient of the hospital or critical access hospital and the reason for status as an outpatient receiving observation services; and

(ii) An explanation of the implications of such status as an outpatient on services furnished by the hospital or critical access hospital (including services furnished on an inpatient basis), such as Medicare cost-sharing requirements, and subsequent eligibility for Medicare coverage for skilled nursing facility services.

(2) *Oral notice.* The hospital must give an oral explanation of the written notification described in paragraph (y)(1) of this section.

(3) *Signature requirements.* The written notice specified in paragraph (y)(1) of this section must either—

(i) Be signed by the individual who receives observation services as an outpatient or a person acting on the individual's behalf to acknowledge receipt of such notification; or

(ii) If the individual who receives observation services as an outpatient or the person acting on behalf of the individual refuses to provide the signature described in paragraph (y)(1) of this section, is signed by the staff member of the hospital or critical access hospital who presented the written notification and includes the name and title of the staff member, a certification that the notification was presented, and the date and time the notification was presented.

Dated: April 1, 2016.

Andrew M. Slavitt,

Administrator, Centers for Medicare & Medicaid Services.

Dated: April 14, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

Note: The following Addendum and Appendixes will not appear in the Code of Federal Regulations.

Addendum—Proposed Schedule of Standardized Amounts, Update Factors, Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning on or After October 1, 2016, and Payment Rates for LTCHs Effective for Discharges Occurring on or After October 1, 2016

I. Summary and Background

In this Addendum, we are setting forth a description of the methods and data we used to determine the proposed prospective payment rates for Medicare hospital inpatient operating costs and Medicare hospital inpatient capital-related costs for FY 2017 for acute care hospitals. We also are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS for FY 2017. We note that, because certain hospitals excluded from the IPPS are paid on a reasonable cost basis subject to a rate-of-increase ceiling (and not by the IPPS), these hospitals are not affected by the proposed figures for the standardized amounts, offsets, and budget neutrality factors. Therefore, in this proposed rule, we are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS that will be effective for cost reporting periods beginning on or after October 1, 2016.

In addition, we are setting forth a description of the methods and data we used to determine the proposed standard Federal payment rate that would be applicable to Medicare LTCHs for FY 2017.

In general, except for SCHs and MDHs, for FY 2017, each hospital's payment per discharge under the IPPS is based on 100 percent of the Federal national rate, also known as the national adjusted standardized amount. This amount reflects the national average hospital cost per case from a base year, updated for inflation.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal national rate (including, as discussed in section IV.F. of the preamble of this proposed rule, uncompensated care payments under section 1886(r)(2) of the Act); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge.

We note that section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted on April 16, 2015) extended the MDH program (which, under previous law, was to be in effect for discharges on or before March 31, 2015 only) for discharges occurring on or after April 1, 2015, through FY 2017 (that is, for discharges occurring on or before September 30, 2017).

Under section 1886(d)(5)(G) of the Act, MDHs historically were paid based on the Federal national rate or, if higher, the Federal national rate plus 50 percent of the difference between the Federal national rate and the updated hospital-specific rate based on FY 1982 or FY 1987 costs per discharge, whichever was higher. However, section 5003(a)(1) of Public Law 109–171 extended and modified the MDH special payment provision that was previously set to expire on October 1, 2006, to include discharges occurring on or after October 1, 2006, but before October 1, 2011. Under section 5003(b) of Public Law 109–171, if the change results in an increase to an MDH's target amount, we must rebase an MDH's hospital-specific rates based on its FY 2002 cost report. Section 5003(c) of Public Law 109–171 further required that MDHs be paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the updated hospital-specific rate. Further, based on the provisions of section 5003(d) of Public Law 109–171, MDHs are no longer subject to the 12-percent cap on their DSH payment adjustment factor.

As discussed in section IV.A. of the preamble of this proposed rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, CMS calculated the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount under the amendments to section 1886(d)(9)(E) of the Act, there is no longer a need for us to calculate a Puerto Rico-specific standardized amount. For operating costs for inpatient hospital discharges occurring in FY 2017 and subsequent fiscal years, consistent with the provisions of section 1886(d)(9)(E) of the Act as amended by section 601 of Public Law 114–113, subsection (d) Puerto Rico hospitals will continue to be paid based on 100 percent of the national standardized amount. Because Puerto Rico hospitals are now paid 100 percent of the national standardized amount and are subject to the same national standardized amount as subsection (d) hospitals that receive the full update, our discussion below does not include references to the Puerto Rico standardized amount or the Puerto Rico-specific wage index.

As discussed in section II. of this Addendum, we are proposing to make changes in the determination of the prospective payment rates for Medicare inpatient operating costs for acute care hospitals for FY 2017. In section III. of this Addendum, we discuss our proposed policy changes for determining the prospective payment rates for Medicare inpatient capital-related costs for FY 2017. In section IV. of this Addendum, we are setting forth the rate-of-increase percentage for determining the rate-of-increase limits for certain hospitals excluded from the IPPS for FY 2017. In section V. of this Addendum, we discuss proposed policy changes for determining the standard Federal rate for LTCHs paid under the LTCH PPS for FY 2017. The tables to which we refer in the preamble of this proposed rule are listed in section VI. of this Addendum and are available via the Internet on the CMS Web site.

II. Proposed Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 2017

The basic methodology for determining prospective payment rates for hospital inpatient operating costs for acute care hospitals for FY 2005 and subsequent fiscal years is set forth under § 412.64. The basic methodology for determining the prospective payment rates for hospital inpatient operating costs for hospitals located in Puerto Rico for FY 2005 and subsequent fiscal years is set forth under §§ 412.211 and 412.212. Below we discuss the factors we are proposing to use for determining the proposed prospective payment rates for FY 2017.

In summary, the proposed standardized amounts set forth in Tables 1A, 1B, and 1C that are listed and published in section VI. of this Addendum (and available via the Internet on the CMS Web site) reflect—

- Equalization of the standardized amounts for urban and other areas at the level computed for large urban hospitals during FY 2004 and onward, as provided for under section 1886(d)(3)(A)(iv)(II) of the Act.
- The labor-related share that is applied to the standardized amounts to give the hospital the highest payment, as provided for under sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act. For FY 2017, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the national standardized amount. We refer readers to section IV.B. of the preamble of this proposed rule for a complete discussion on the proposed FY 2017 inpatient hospital update. Below is a table with these four options:

FY 2017	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Proposed Market Basket Rate-of-Increase	2.8	2.8	2.8	2.8
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.7	−0.7
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−2.1	0.0	−2.1
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.6	−0.5	−0.5	−0.5
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.75	−0.75	−0.75	−0.75
Proposed Applicable Percentage Increase Applied to Standardized Amount	1.55	−0.55	0.85	−1.25

We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for "subsection (d)" hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.

In addition, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016, and also to apply the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act to Puerto Rico hospitals that are not meaningful EHR users, effective FY 2022. Accordingly, because the provisions of section 1886(b)(3)(B)(ix) of the Act are not applicable to hospitals located in Puerto Rico until FY 2022, the adjustments under this provision are not applicable for FY 2017.

- An adjustment to the standardized amount to ensure budget neutrality for DRG recalibration and reclassification, as provided for under section 1886(d)(4)(C)(iii) of the Act.
- An adjustment to ensure the wage index changes are budget neutral, as provided for under section 1886(d)(3)(E)(i) of the Act. We note that section 1886(d)(3)(E)(i) of the Act requires that when we compute such budget neutrality, we assume that the provisions of section 1886(d)(3)(E)(ii) of the Act (requiring a 62-percent labor-related share in certain circumstances) had not been enacted.
- An adjustment to ensure the effects of geographic reclassification are budget neutral, as provided for under section 1886(d)(8)(D) of the Act, by removing the FY 2016 budget neutrality factor and applying a revised factor.
- As discussed below and in section III.G. of the preamble of this proposed rule, an adjustment to offset the cost of the 3-year hold harmless transitional wage index provisions provided by CMS as a result of the implementation of the new OMB labor market area delineations (beginning with FY 2015).
- An adjustment to remove the FY 2016 outlier offset and apply an offset for FY 2017, as provided for under section 1886(d)(3)(B) of the Act.
- As discussed below and in section II.D. of the preamble of this proposed rule, a recoupment to meet the requirements of section 631 of ATRA to adjust the standardized amount to offset the estimated amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013.
- As discussed below and in section IV.O. of the preamble of this proposed rule, we are proposing a (1/0.998) adjustment to the standardized amount using our authority under sections 1886(d)(5)(I)(i) and 1886(g) of the Act to permanently prospectively remove the 0.2 percent reduction to the rate put in place in FY 2014 to offset the estimated increase in IPPS expenditures associated with the projected increase in inpatient encounters that was expected to result from the new inpatient admission guidelines under the 2-midnight policy.
- As discussed below and in section IV.O. of the preamble of this proposed rule, we are proposing a temporary one-time prospective increase to the FY 2017 rates of 0.6 percent or a factor of 1.006 using our authority under sections 1886(d)(5)(I)(i) and 1886(g) of the Act to address the effects of the 0.2 percent reduction to the rate for the 2-midnight policy in effect for FY 2014, FY 2015, and FY 2016.

For FY 2017, consistent with current law, we are applying the rural floor budget neutrality adjustment to hospital wage indexes. Also, consistent with section 3141 of the Affordable Care Act, instead of applying a State-level rural floor budget neutrality adjustment to the wage index, we are applying a uniform, national budget neutrality adjustment to the FY 2017 wage index for the rural floor. We note that, in section III.H.2.b. of the preamble to this proposed rule, we are proposing to extend the imputed floor policy (both the original methodology and alternative methodology) for FY 2017. Therefore, for FY 2017, in this proposed rule, we are proposing to continue to include the imputed floor (calculated under the original and alternative methodologies) in calculating the uniform, national rural floor budget neutrality adjustment, which would be reflected in the FY 2017 wage index.

In prior fiscal years, CMS made an adjustment to ensure the effects of the rural community hospital demonstration program required under section 410A of Public Law 108–173, as amended by sections 3123 and 10313 of Public Law 111–148, which extended the demonstration program for an additional 5 years (FYs 2011 through 2016), were budget neutral as required under section 410A(c)(2) of Public Law 108–173. As discussed in section IV.K.3. of the preamble to this proposed rule, given the small number of participating hospitals and the limited time of participation during FY 2017, we are proposing to forego the process of estimating the costs attributable to the demonstration for FY 2017 and to instead analyze the set of finalized cost reports for reporting periods beginning in FY 2016 when they become available. In addition, we discuss how we would reconcile the budget neutrality offset amounts identified in the IPPS final rules for FYs 2011 through 2016 with the actual costs of the demonstration for those years, considering the fact that the demonstration will end December 31, 2016. We stated that we believe it would be appropriate to conduct this analysis for FYs 2011 through 2016 at one time, when all of the finalized cost reports for cost reporting periods beginning in FYs 2011 through 2016 are available. Such an aggregate analysis encompassing the cost experience through the end of the period of performance of the demonstration represents an administratively streamlined method, allowing for the determination of any appropriate final adjustment to the IPPS rates and obviating the need for multiple fiscal-year-specific calculations and regulatory actions. Given the general lag of 3 years in finalizing cost reports, we expect any such analysis to be conducted in FY 2020. Therefore, for FY 2017 we are not proposing to make any adjustment to the standardized amounts for the rural community hospital demonstration program. We refer the reader to section IV.K. of the preamble of this proposed rule for a complete discussion on the rural community hospital demonstration program.

A. Calculation of the Proposed Adjusted Standardized Amount

1. Standardization of Base-Year Costs or Target Amounts

In general, the national standardized amount is based on per discharge averages of adjusted hospital costs from a base period (section 1886(d)(2)(A) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d) of the Act. The September 1, 1983 interim final rule (48 FR 39763) contained a detailed explanation of how base-year cost data (from cost reporting periods ending during FY 1981) were established for urban and rural hospitals in the initial development of standardized amounts for the IPPS.

Sections 1886(d)(2)(B) and 1886(d)(2)(C) of the Act requires us to update base-year per discharge costs for FY 1984 and then standardize the cost data in order to remove the effects of certain sources of cost variations among hospitals. These effects include case-mix, differences in area wage levels, cost-of-living adjustments for Alaska and Hawaii, IME costs, and costs to hospitals serving a disproportionate share of low-income patients.

For FY 2017, we are proposing to continue to use the national labor-related and nonlabor-related shares (which are based on the FY 2010-based hospital market basket) that was used in FY 2016. Specifically, under section 1886(d)(3)(E) of the Act, the Secretary estimates, from time to time, the proportion of payments that are labor-related and adjusts the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the proportion of hospitals' costs that are attributable to wages and wage-related costs as the "labor-related share." For FY 2017, as discussed in section III. of the preamble of this proposed rule, we are proposing to continue to use a labor-related share of 69.6 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000

The proposed standardized amounts for operating costs appear in Tables 1A, 1B, and 1C that are listed and published in section VI. of the Addendum to this proposed rule and are available via the Internet on the CMS Web site.

2. Computing the National Average Standardized Amount

Section 1886(d)(3)(A)(iv)(II) of the Act requires that, beginning with FY 2004 and thereafter, an equal standardized amount be computed for all hospitals at the level computed for large urban hospitals during FY 2003, updated by the applicable percentage update. Accordingly, we are proposing to calculate the FY 2017 national average standardized amount irrespective of whether a hospital is located in an urban or rural location.

3. Updating the National Average Standardized Amount

Section 1886(b)(3)(B) of the Act specifies the applicable percentage increase used to update the standardized amount for payment for inpatient hospital operating costs. We note that, in compliance with section 404 of the MMA, in this proposed rule, we are proposing to use the revised and rebased FY 2010-based IPPS operating and capital market baskets for FY 2017 (which replaced the FY 2006-based IPPS operating and capital market baskets in FY 2014). As discussed in section IV.B. of the preamble of this proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are proposing to reduce the FY 2017 applicable percentage increase (which is based on IHS Global Insight, Inc.'s (IGI's) first quarter 2016 forecast of the FY 2010-based IPPS market basket) by the MFP adjustment (the 10-year moving average of MFP for the period ending FY 2017) of 0.5 percentage point, which is calculated based on IGI's first quarter 2016 forecast.

In addition, in accordance with section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are proposing to further update the standardized amount for FY 2017 by the estimated market basket percentage increase less 0.75 percentage point for hospitals in all areas. Sections 1886(b)(3)(B)(xi) and (xii) of the Act, as added and amended by sections 3401(a) and 10319(a) of the Affordable Care Act, further state that these adjustments may result in the applicable percentage increase being less than zero. The percentage increase in the market basket reflects the average change in the price of goods and services comprising routine, ancillary, and special care unit hospital inpatient services.

Based on IGI's 2016 first quarter forecast of the hospital market basket increase (as discussed in Appendix B of this proposed rule), the most recent forecast of the hospital market basket increase for FY 2017 is 2.8 percent. As discussed earlier, for FY 2017, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act, there are four possible applicable percentage increases that could be applied to the standardized amount. We refer readers to section IV.B. of the preamble of this proposed rule for a complete discussion on the proposed FY 2017 inpatient hospital update to the standardized amount. We also refer readers to the table above for the four possible applicable percentage increases that would be applied to update the national standardized amount. The proposed standardized amounts shown in Tables 1A through 1C that are published in section VI. of this Addendum and that are available via the Internet on the CMS Web site reflect these differential amounts.

Although the update factors for FY 2017 are set by law, we are required by section 1886(e)(4) of the Act to recommend, taking into account MedPAC's recommendations, appropriate update factors for FY 2017 for both IPPS hospitals and hospitals and hospital units excluded from the IPPS. Section 1886(e)(5)(A) of the Act requires that we publish our proposed recommendations in the **Federal Register** for public comment. Our recommendation on the update factors is set forth in Appendix B of this proposed rule.

4. Methodology for Calculation of the Average Standardized Amount

The methodology we used to calculate the proposed FY 2017 standardized amount is as follows:

- To ensure we are only including hospitals paid under the IPPS in the calculation of the standardized amount, we apply the following inclusion and exclusion criteria: include hospitals whose last four digits fall between 0001 and 0879 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS Web site at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); exclude critical access hospitals at the time of this proposed rule; exclude hospitals in Maryland (because these hospitals are paid under an all payer model under section 1115A of the Act); and remove PPS-excluded cancer hospitals that have a "V" in the fifth position of their provider number or a "E" or "F" in the sixth position.

- As in the past, we are proposing to adjust the FY 2017 standardized amount to remove the effects of the FY 2016 geographic reclassifications and outlier payments before applying the FY 2017 updates. We then apply budget neutrality offsets for outliers and geographic reclassifications to the standardized amount based on proposed FY 2017 payment policies.
- We do not remove the prior year's budget neutrality adjustments for reclassification and recalibration of the DRG relative weights and for updated wage data because, in accordance with sections 1886(d)(4)(C)(iii) and 1886(d)(3)(E) of the Act, estimated aggregate payments after updates in the DRG relative weights and wage index should equal estimated aggregate payments prior to the changes. If we removed the prior year's adjustment, we would not satisfy these conditions.

Budget neutrality is determined by comparing aggregate IPPS payments before and after making changes that are required to be budget neutral (for example, changes to MS–DRG classifications, recalibration of the MS–DRG relative weights, updates to the wage index, and different geographic reclassifications). We include outlier payments in the simulations because they may be affected by changes in these parameters.

- Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50433), because IME Medicare Advantage payments are made to IPPS hospitals under section 1886(d) of the Act, we believe these payments must be part of these budget neutrality calculations. However, we note that it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation or the outlier offset to the standardized amount because the statute requires that outlier payments be not less than 5 percent nor more than 6 percent of total "operating DRG payments," which does not include IME and DSH payments. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.
- Consistent with the methodology in the FY 2012 IPPS/LTCH PPS final rule, in order to ensure that we capture only fee-for-service claims, we are only including claims with a "Claim Type" of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).
- In order to further ensure that we capture only FFS claims, we are proposing to exclude claims with a "GHOPAID" indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).
- Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50423), we examine the MedPAR file and remove pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of "3" for blood clotting with a revenue code of "0636" from the covered charge field for the budget neutrality adjustments. We also remove organ acquisition charges from the covered charge field for the budget neutrality adjustments because organ acquisition is a pass-through payment not paid under the IPPS.
- The Bundled Payments for Care Improvement (BPCI) initiative, developed under the authority of section 3021 of the Affordable Care Act (codified at section 1115A of the Act), is comprised of four broadly defined models of care, which link payments for multiple services beneficiaries receive during an episode of care. Under the BPCI initiative, organizations enter into payment arrangements that include financial and performance accountability for episodes of care. On January 31, 2013, CMS announced the first set of health care organizations selected to participate in the BPCI initiative. Additional organizations were selected in 2014. For additional information on the BPCI initiative, we refer readers to the CMS Center for Medicare and Medicaid Innovation's Web site at: *http://innovation.cms.gov/initiatives/Bundled-Payments/index.html.*

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53341 through 53343), for FY 2013 and subsequent fiscal years, we finalized a methodology to treat hospitals that participate in the BPCI initiative the same as prior fiscal years for the IPPS payment modeling and ratesetting process (which includes recalibration of the MS–DRG relative weights, ratesetting, calculation of the budget neutrality factors, and the impact analysis) without regard to a hospital's participation within these bundled payment models (that is, as if they are not participating in those models under the BPCI initiative). For FY 2017, we are proposing to continue to include all applicable data from subsection (d) hospitals participating in BPCI Models 1, 2, and 4 in our IPPS payment modeling and ratesetting calculations.

- Consistent with our methodology established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688), we believe that it is appropriate to include adjustments for the Hospital Readmissions Reduction Program and the Hospital VBP Program (established under the Affordable Care Act) within our budget neutrality calculations.

Both the hospital readmissions payment adjustment (reduction) and the hospital VBP payment adjustment (redistribution) are applied on a claim-by-claim basis by adjusting, as applicable, the base-operating DRG payment amount for individual subsection (d) hospitals, which affects the overall sum of aggregate payments on each side of the comparison within the budget neutrality calculations.

In order to properly determine aggregate payments on each side of the comparison, as we have done for the last 3 fiscal years, for FY 2017 and subsequent years, we are proposing to continue to apply the hospital readmissions payment adjustment and the hospital VBP payment adjustment on each side of the comparison, consistent with the methodology that we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688). That is, we are proposing to apply the proposed readmissions payment adjustment factor and the proposed hospital VBP payment adjustment factor on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

For the purpose of calculating the proposed FY 2017 readmissions payment adjustment factors, we are proposing to use excess readmission ratios and aggregate payments for excess readmissions based on admissions from the prior fiscal year's applicable period because hospitals have had the opportunity to review and correct these data before the data were made public under the policy we adopted regarding the reporting of hospital-specific readmission rates, consistent with section 1886(q)(6) of the Act. For FY 2017, in this proposed rule, we are proposing to calculate the readmissions payment adjustment factors using excess readmission ratios and aggregate payments for excess readmissions based on admissions from the finalized applicable period for FY 2017 as hospitals have had the opportunity to review and correct these data under our policy regarding the reporting of hospital-specific readmission rates consistent with section 1886(q)(6) of the Act. We discuss our proposed policy regarding the reporting of hospital-specific readmission rates for FY 2017 in section IV.G.3.f of the preamble of this proposed rule. (For additional information on our general policy for the reporting of hospital-specific readmission rates, consistent with section 1886(q)(6) of the Act, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53399 through 53400).)

In addition, for FY 2017, in this proposed rule, for the purpose of modeling aggregate payments when determining all budget neutrality factors, we are proposing to use proxy hospital VBP payment adjustment factors for FY 2017 that are based on data from a historical period because hospitals have not yet had an opportunity to review and submit corrections for their data from the FY 2017 performance period. (For additional information on our policy regarding the review and correction of hospital-specific measure rates under the Hospital VBP Program, consistent with section 1886(o)(10)(A)(ii) of the Act, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53578 through 53581), the CY 2012 OPPS/ASC final rule with comment period (76 FR 74544 through 74547), and the Hospital Inpatient VBP final rule (76 FR 26534 through 26536).)

- The Affordable Care Act also established section 1886(r) of the Act, which modifies the methodology for computing the Medicare DSH payment adjustment beginning in FY 2014. Beginning in FY 2014, IPPS hospitals receiving Medicare DSH payment adjustments will receive an empirically justified Medicare DSH payment equal to 25 percent of the amount that would previously have been received under the statutory formula set forth under section 1886(d)(5)(F) of the Act governing the Medicare DSH payment adjustment. In accordance with section 1886(r)(2) of the Act, the remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals under age 65 who are uninsured and an additional statutory adjustment, will be available to make additional payments to Medicare DSH hospitals based on their share of the total amount of uncompensated care reported by Medicare DSH hospitals for a given time period. In order to properly determine aggregate payments on each side of the comparison for budget neutrality, prior to FY 2014, we included estimated Medicare DSH payments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

To do this for FY 2017 (as we did for the last 3 fiscal years), we are proposing to include estimated empirically justified Medicare DSH payments that will be paid in accordance with section 1886(r)(1) of the Act and estimates of the additional uncompensated care payments made to hospitals receiving Medicare DSH payment adjustments as described by section 1886(r)(2) of the Act. That is, we are proposing to consider estimated empirically justified Medicare DSH payments at 25 percent of what would otherwise have been paid, and also the estimated additional uncompensated care payments for hospitals receiving Medicare DSH payment adjustments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

- When calculating total payments for budget neutrality, to determine total payments for SCHs, we model total hospital-specific rate payments and total Federal rate payments and then include whichever one of the total payments is greater. As discussed in section IV.F. of the preamble to this proposed rule and below, we are proposing to continue the FY 2014 finalized methodology under which we would take into consideration uncompensated care payments in the comparison of payments under the Federal rate and the hospital-specific rate for SCHs. Therefore, we are proposing to include estimated uncompensated care payments in this comparison.

Similarly, for MDHs, as discussed in section IV. of the preamble to this proposed rule, when computing payments under the Federal national rate plus 75 percent of the difference between the payments under the Federal national rate and the payments under the updated hospital-specific rate, we are continuing to take into consideration uncompensated care payments in the computation of payments under the Federal rate and the hospital-specific rate for MDHs.

- We are proposing to include an adjustment to the standardized amount for those hospitals that are not meaningful EHR users in our modeling of aggregate payments for budget neutrality for FY 2017. Similar to FY 2016, we are including this adjustment based on data on the prior year's performance. Payments for hospitals would be estimated based on the proposed applicable standardized amount in Tables 1A and 1B for discharges occurring in FY 2017.

a. Proposed Recalibration of MS–DRG Relative Weights

Section 1886(d)(4)(C)(iii) of the Act specifies that, beginning in FY 1991, the annual DRG reclassification and recalibration of the relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. As discussed in section II.G. of the preamble of this proposed rule, we normalized the recalibrated MS–DRG relative weights by an adjustment factor so that the average case relative weight after recalibration is equal to the average case relative weight prior to recalibration. However, equating the average case relative weight after recalibration to the average case relative weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate payments to hospitals because payments to hospitals are affected by factors other than average case relative weight. Therefore, as we have done in past years, we are proposing to make a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

For FY 2017, to comply with the requirement that MS–DRG reclassification and recalibration of the relative weights be budget neutral for the standardized amount and the hospital-specific rates, we used FY 2015 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2016 labor-related share percentages, the FY 2016 relative weights, and the FY 2016 pre-reclassified wage data, and applied the proposed FY 2017 hospital readmissions payment adjustments and estimated FY 2017 hospital VBP payment adjustments; and
- Aggregate payments using the FY 2016 labor-related share percentages, the proposed FY 2017 relative weights, and the FY 2016 pre-reclassified wage data, and applied the same proposed FY 2017 hospital readmissions payment adjustments and estimated FY 2017 hospital VBP payment adjustments applied above.

Based on this comparison, we computed a proposed budget neutrality adjustment factor equal to 0.999006 and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, we also are proposing to apply the MS–DRG reclassification and recalibration budget neutrality factor of 0.999006 to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2016.

b. Updated Wage Index—Budget Neutrality Adjustment

Section 1886(d)(3)(E)(i) of the Act requires us to update the hospital wage index on an annual basis beginning October 1, 1993. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. Section 1886(d)(3)(E)(i) of the Act requires that we implement the wage index adjustment in a budget neutral manner. However, section 1886(d)(3)(E)(ii) of the Act sets the labor-related share at 62 percent for hospitals with a wage index less than or equal to 1.0000, and section 1886(d)(3)(E)(i) of the Act provides that the Secretary shall calculate the budget neutrality adjustment for the adjustments or updates made under that provision as if section 1886(d)(3)(E)(ii) of the Act had not been enacted. In other words, this section of the statute requires that we implement the updates to the wage index in a budget neutral manner, but that our budget neutrality adjustment should not take into account the requirement that we set the labor-related share for hospitals with wage indexes less than or equal to 1.0000 at the more advantageous level of 62 percent. Therefore, for purposes of this budget neutrality adjustment, section 1886(d)(3)(E)(i) of the Act prohibits us from taking into account the fact that hospitals with a wage index less than or equal to 1.0000 are paid using a labor-related share of 62 percent. Consistent with current policy, for FY 2017, we are proposing to adjust 100 percent of the wage index factor for occupational mix. We describe the occupational mix adjustment in section III.E. of the preamble of this proposed rule.

To compute a proposed budget neutrality adjustment factor for wage index and labor-related share percentage changes, we used FY 2015 discharge data to simulate payments and compared the following:

- Aggregate payments using the proposed FY 2017 relative weights and the FY 2016 pre-reclassified wage indexes, applied the FY 2016 labor-related share of 69.6 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the proposed FY 2017 hospital readmissions payment adjustment and the estimated FY 2017 hospital VBP payment adjustment; and
- Aggregate payments using the proposed FY 2017 relative weights and the proposed FY 2017 pre-reclassified wage indexes, applied the proposed labor-related share for FY 2017 of 69.6 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the same proposed FY 2017 hospital readmissions payment adjustments and estimated FY 2017 hospital VBP payment adjustments applied above.

In addition, we applied the proposed MS–DRG reclassification and recalibration budget neutrality adjustment factor (derived in the first step) to the payment rates that were used to simulate payments for this comparison of aggregate payments from FY 2016 to FY 2017. By applying this methodology, we determined a proposed budget neutrality adjustment factor of 0.999785 for proposed changes to the wage index.

We note that, in prior fiscal years, we used a three-step process and combined the recalibration and wage index budget neutrality factors into one factor by multiplying the recalibration adjustment factor by the wage index adjustment factor. Because these two adjustments are required under two different sections of the Act (sections 1886(d)(4)(C)(iii) and 1886(d)(3)(E)(i) of the Act) and the law requires that the wage index budget neutrality adjustment not take into account the requirement that we set the labor-related share for hospitals with wage indexes less than or equal to 1.0000 at the more advantageous level of 62 percent for FY 2017, we are proposing to separate these two adjustments and apply them individually to the standardized amount. Applying these factors individually rather than as a combined factor has no effect mathematically on adjusting the standardized amount.

c. Reclassified Hospitals—Proposed Budget Neutrality Adjustment

Section 1886(d)(8)(B) of the Act provides that certain rural hospitals are deemed urban. In addition, section 1886(d)(10) of the Act provides for the reclassification of hospitals based on determinations by the MGCRB. Under section 1886(d)(10) of the Act, a hospital may be reclassified for purposes of the wage index.

Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amount to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. We note that the wage index adjustments provided for under section 1886(d)(13) of the Act are not budget neutral. Section 1886(d)(13)(H) of the Act provides that any increase in a wage index under section 1886(d)(13) shall not be taken into account in applying any budget neutrality adjustment with respect to such index under section 1886(d)(8)(D) of the Act. To calculate the proposed budget neutrality adjustment factor for FY 2017, we used FY 2015 discharge data to simulate payments and compared the following:

- Aggregate payments using the proposed FY 2017 labor-related share percentages, proposed FY 2017 relative weights and proposed FY 2017 wage data prior to any reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, and applied the proposed FY 2017 hospital readmissions payment adjustments and the estimated FY 2017 hospital VBP payment adjustments; and
- Aggregate payments using the proposed FY 2017 labor-related share percentages, proposed FY 2017 relative weights, and proposed FY 2017 wage data after such reclassifications, and applied the same proposed FY 2017 hospital readmissions payment adjustments and the estimated FY 2017 hospital VBP payment adjustments applied above.

We note that the reclassifications applied under the second simulation and comparison are those listed in Table 2 associated with this proposed rule, which is available via the Internet on the CMS Web site. This table reflects reclassification crosswalks proposed for FY 2017, and apply the proposed policies explained in section III. of the preamble to this proposed rule. Based on these simulations, we calculated a proposed budget neutrality adjustment factor of 0.988816 to ensure that the effects of these provisions are budget neutral, consistent with the statute.

The proposed FY 2017 budget neutrality adjustment factor was applied to the standardized amount after removing the effects of the FY 2016 budget neutrality adjustment factor. We note that the proposed FY 2017 budget neutrality adjustment reflects FY 2017 wage index reclassifications approved by the MGCRB or the Administrator at the time of development of the proposed rule.

d. Proposed Rural Floor Budget Neutrality Adjustment

Under § 412.64(e)(4), we make an adjustment to the wage index to ensure that aggregate payments after implementation of the rural floor under section 4410 of the BBA (Pub. L. 105–33) and the imputed floor under § 412.64(h)(4) are equal to the aggregate prospective payments that would have been made in the absence of such provisions. Consistent with section 3141 of the Affordable Care Act and as discussed in section III.H. of the preamble of this proposed rule and codified at § 412.64(e)(4)(ii), the budget neutrality adjustment for the rural floor and the imputed floor is a national adjustment to the wage index.

As noted above and as discussed in section III.H.2. of the preamble of this proposed rule, we are proposing to extend the imputed floor policy (both the original methodology and alternative methodology) for FY 2017. Therefore, in order to ensure that aggregate payments to hospitals are not affected, similar to prior years, for FY 2017, we would follow our policy of including the proposed imputed floor (calculated under the original and alternative methodologies) in the proposed national rural floor budget neutrality adjustment to the wage index.

Similar to our calculation in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50369 through 50370), for FY 2017, we are proposing to calculate a national rural Puerto Rico wage index. Because there are no rural Puerto Rico hospitals with established wage data, our calculation of the proposed FY 2017 rural Puerto Rico wage index is based on the policy adopted in the FY 2008 IPPS final rule with comment period (72 FR 47323). That is, we will use the unweighted average of the wage indexes from all CBSAs (urban areas) that are contiguous (share a border with) to the rural counties to compute the rural floor (72 FR 47323; 76 FR 51594). Under the new OMB labor market area delineations, except for Arecibo, Puerto Rico (CBSA 11640), all other Puerto Rico urban areas are contiguous to a rural area. Therefore, based on our existing policy, the proposed FY 2017 rural Puerto Rico wage index is calculated based on the average of the proposed FY 2017 wage indexes for the following urban areas: Aguadilla-Isabela, PR (CBSA 10380); Guayama, PR (CBSA 25020); Mayaguez, PR (CBSA 32420); Ponce, PR (CBSA 38660), San German, PR (CBSA 41900) and San Juan-Carolina-Caguas, PR (CBSA 41980).

To calculate the national rural floor and imputed floor budget neutrality adjustment factor, we are proposing to use FY 2015 discharge data to simulate payments and the proposed post-reclassified national wage indexes and compared the following:

- National simulated payments without the proposed national rural floor and imputed floor; and
- National simulated payments with the proposed national rural floor and imputed floor.

Based on this comparison, we determined a proposed national rural floor and imputed floor budget neutrality adjustment factor of 0.993806. The national adjustment was applied to the national wage indexes to produce a proposed national rural floor and imputed floor budget neutral wage index.

e. Wage Index Transition Budget Neutrality

As discussed in section III.G. of the preamble of this proposed rule, in the past, we have provided for transition periods when adopting changes that have significant payment implications, particularly large negative impacts.

Similar to FY 2005, for FY 2015, we determined that the transition to using the new OMB labor market area delineations would have the largest impact on hospitals that were located in an urban county that became rural under the new OMB delineations or hospitals deemed urban where the urban area became rural under the new OMB delineations. To alleviate the decreased payments associated with having a rural wage index, in calculating the area wage index, similar to the transition provided in the FY 2005 IPPS final rule, we finalized a policy to generally assign the hospitals in these counties the urban wage index value of the CBSA where they are physically located in for FY 2014 for FYs 2015, 2016, and 2017. FY 2017 will be the final year of this 3-year transition policy. We note that the 1-year blended wage index transitional policy for all hospitals that would experience any decrease in their wage index value expired in FY 2015.

As discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50372 through 50373), in the past, CMS has budget neutralized transitional wage indexes. We stated that because we established a policy that allows for the application of a transitional wage index only when it benefits the hospital, we believe that it would be appropriate to ensure that such a transitional policy does not increase aggregate Medicare payments beyond the payments that would be made had we simply adopted the OMB delineations without any transitional provisions. Therefore, as we did for FYs 2015 and 2016, for FY 2017, we are proposing to use our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to make an adjustment to the national standardized amounts to ensure that total payments for the effect of the 3-year transitional wage index provisions would equal what payments would have been if we had fully adopted the new OMB delineations without providing these transitional provisions. To calculate the proposed transitional wage index budget neutrality factor for FY 2017, we used FY 2015 discharge data to simulate payments and compared the following:

- Aggregate payments using the OMB delineations for FY 2017, the proposed FY 2017 relative weights, proposed FY 2017 wage data after such reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, application of the proposed rural floor budget neutrality adjustment factor to the wage index, and application of the proposed FY 2017 hospital readmissions payment adjustments and the estimated FY 2017 hospital VBP payment adjustments; and
- Aggregate payments using the OMB delineations for FY 2017, the proposed FY 2017 relative weights, proposed FY 2017 wage data after such reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, application of the proposed rural floor budget neutrality adjustment factor to the wage index, application of the 3-year transitional wage indexes, and application of the same proposed FY 2017 hospital readmissions payment adjustments and the estimated FY 2017 hospital VBP payment adjustments applied above.

Based on these simulations, we calculated a proposed budget neutrality adjustment factor of 0.999999. Therefore, for FY 2017, we are proposing to apply a transitional wage index budget neutrality adjustment factor of 0.999999 to the national average standardized amounts to ensure that the effects of these proposed transitional wage indexes are budget neutral.

We note that the proposed budget neutrality adjustment factor calculated above is based on the increase in payments in FY 2017 that would result from the final year of the 3-year transitional wage index policies. Therefore, we are proposing to apply this proposed budget neutrality adjustment factor as a one-time adjustment to the FY 2017 national standardized amounts in order to offset the increase in payments in FY 2017 as a result of this final year of the 3-year transitional wage index. For FY 2017, we did not take into consideration the adjustment factor applied to the national standardized amounts in the previous fiscal year's update when calculating the current fiscal year transitional wage index budget neutrality adjustment factor (that is, this adjustment is not applied cumulatively).

f. Proposed Case-Mix Budget Neutrality Adjustment

(1) Background

Below we summarize the proposed recoupment adjustment to the FY 2017 payment rates, as required by section 631 of ATRA, to account for the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013. We refer readers to section II.D. of the preamble of this proposed rule for a complete discussion regarding our proposed policies for FY 2017 in this proposed rule and previously finalized policies (including our historical adjustments to the payment rates) relating to the effect of changes in documentation and coding that do not reflect real changes in case-mix.

(2) Recoupment or Repayment Adjustment Authorized by Section 631 of the American Taxpayer Relief Act of 2012 (ATRA) to the National Standardized Amount

Section 631 of the ATRA amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment totaling $11 billion by FY 2017. Our actuaries estimated that if CMS were to fully account for the $11 billion recoupment required by section 631 of ATRA in FY 2014, a one-time −9.3 percent adjustment to the standardized amount would be necessary. It is often our practice to delay or phase-in payment rate adjustments over more than 1 year, in order to moderate the effect on payment rates in any 1 year. Therefore, consistent with the policies that we have adopted in many similar cases, for FY 2014, FY 2015 and FY 2016, we applied a −0.8 percent adjustment to the standardized amount. For FY 2017, we are proposing to apply a −1.5 percent adjustment to the standardized amount. We refer the reader to section II. D. 6 of the preamble to this proposed rule for a complete discussion on this adjustment. We note that, as section 631 of the ATRA instructs the Secretary to make a recoupment adjustment only to the standardized amount, this adjustment would not apply to the hospital-specific payment rates.

g. Proposed Adjustment to IPPS Rates Resulting From 2-Midnight Policy

As discussed in section IV. O of the preamble to this proposed rule, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50906 through 50954), we adopted the 2-midnight policy effective for dates of admission on or after October 1, 2013. We used our authority under section 1886(d)(5)(I)(i) of the Act to make a reduction of 0.2 percent to the standardized amount, the Puerto Rico standardized amount, and the hospital-specific payment rate, and we used our authority under section 1886(g) of the Act to make a reduction of 0.2 percent to the national capital Federal rate and the Puerto Rico-specific capital rate, in order to offset the estimated increase of $220 million in IPPS expenditures in FY 2014 as a result of the 2-midnight policy.

In *Shands Jacksonville Medical Center, Inc.* v. *Burwell*, No. 14–263 (D.D.C.) and consolidated cases, hospitals challenged the 0.2 percent reduction in IPPS rates to account for the estimated $220 million in additional FY 2014 expenditures resulting from the 2-midnight policy. In its Memorandum Opinion, issued September 21, 2015, the Court found that the "Secretary's interpretation of the exceptions and adjustments provision is a reasonable one" for this purpose. However, the Court also ordered the 0.2 percent reduction remanded back to the Secretary, without vacating the rule, to correct certain procedural deficiencies in the promulgation of the 0.2 percent reduction and reconsider the adjustment. In accordance with the Court's order, we published a notice with comment period that appeared in the December 1, 2015 **Federal Register** (80 FR 75107), which discussed the basis for the 0.2 percent reduction and its underlying assumptions and invited comments on the same in order to facilitate our further consideration of the FY 2014 reduction.

We still believe the assumptions underlying the 0.2 percent reduction to the rates put in place beginning in FY 2014 were reasonable at the time we made them in 2013. Nevertheless, taking all the factors discussed in section IV. O of the preamble to this proposed rule into account and in the context of the litigation, we believe it would be appropriate to use our authority under section 1886(d)(5)(I)(i) to prospectively remove, beginning in FY 2017, the 0.2 percent reduction to the standardized amount and hospital-specific rates put in place beginning in FY 2014. The 0.2 percent reduction was implemented by including a factor of 0.998 in the calculation of the FY 2014 standardized amount and hospital-specific rates, permanently reducing the standardized amount and hospital-specific rates for FY 2014 and future years until the 0.998 is removed. We are proposing to permanently remove the 0.998 reduction beginning in FY 2017 by including a factor of (1/0.998) in the calculation of the FY 2017 standardized amount and hospital specific rate.

In addition, for the reasons discussed in section IV.O. of the preamble of this proposed rule, we believe it would be appropriate to use our authority under section 1886(d)(5)(I)(i) to temporarily increase the standardized amount and hospital-specific rates, only for FY 2017, to address the effect of the 0.2 percent reduction to the standardized amount and hospital-specific rates in effect for FY 2014, the 0.2 percent reduction to the standardized amount and hospital-specific rates in effect for FY 2015 (recall the 0.998 factor included in the calculation of the FY 2014 rates permanently reduced the rates for FY 2014 and future years until it is removed), and the 0.2 percent reduction to the standardized amount and hospital-specific rates in effect for FY 2016. We believe that the most transparent, expedient, and administratively feasible method to accomplish this is a temporary one-time prospective increase to the FY 2017 standardized amount and hospital-specific rates of 0.6 percent (= 0.2 percent + 0.2 percent + 0.2 percent). Specifically, we are proposing to include a factor of 1.006 in the calculation of the standardized amount and the hospital-specific rates in FY 2017 and then remove this temporary one-time prospective increase by including a factor of (1/1.006) in the calculation of the standardized amount and hospital-specific rates for FY 2018.

We refer the reader to section IV.O. of the preamble to this proposed rule for a complete discussion.

h. Proposed Outlier Payments

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for "outlier" cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs greater than the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, any new technology add-on payments, and the "outlier threshold" or "fixed-loss" amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment). We refer to the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, any new technology add-on payments, and the outlier threshold as the outlier "fixed-loss cost threshold." To determine whether the costs of a case exceed the fixed-loss cost threshold, a hospital's CCR is applied to the total covered charges for the case to convert the charges to estimated costs. Payments for eligible cases are then made based on a marginal cost factor, which is a percentage of the estimated costs above the fixed-loss cost threshold. The marginal cost factor for FY 2017 is 80 percent, or 90 percent for burn MS–DRGs 927, 928, 929, 933, 934 and 935. We have used a marginal cost factor of 90 percent since FY 1989 (54 FR 36479 through 36480) for designated burn DRGs as well as a marginal cost factor of 80 percent for all other DRGs since FY 1995 (59 FR 45367).

In accordance with section 1886(d)(5)(A)(iv) of the Act, outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments (which does not include IME and DSH payments) plus outlier payments. When setting the outlier threshold, we compute the 5.1 percent target by dividing the total operating outlier payments by the total operating DRG payments plus outlier payments. We do not include any other payments such as IME and DSH within the outlier target amount. Therefore, it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation. Section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amount by a factor to account for the estimated proportion of total DRG payments made to outlier cases. More information on outlier payments may be found on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/outlier.htm.*

(1) Proposed FY 2017 Outlier Fixed-Loss Cost Threshold

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50977 through 50983), in response to public comments on the FY 2013 IPPS/LTCH PPS proposed rule, we made changes to our methodology for projecting the outlier fixed-loss cost threshold for FY 2014. We refer readers to the FY 2014 IPPS/LTCH PPS final rule for detailed discussion of the changes.

As we have done in the past, to calculate the proposed FY 2017 outlier threshold, we simulated payments by applying proposed FY 2017 payment rates and policies using cases from the FY 2015 MedPAR file. Therefore, in order to determine the proposed FY 2017 outlier threshold, we inflated the charges on the MedPAR claims by 2 years, from FY 2015 to FY 2017. As discussed in the FY 2015 IPPS/LTCH PPS final rule, we believe a methodology that is based on 1-year of charge data will provide a more stable measure to project the average charge per case because our prior methodology used a 6-month measure, which inherently uses fewer claims than a 1-year measure and makes it more susceptible to fluctuations in the average charge per case as a result of any significant charge increases or decreases by hospitals. The methodology we are proposing to calculate the charge inflation factor for FY 2017 and subsequent fiscal years is as follows:

- To produce the most stable measure of charge inflation, we applied the following inclusion and exclusion criteria of hospitals claims in our measure of charge inflation: include hospitals whose last four digits fall between 0001 and 0899 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS Web site at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); include CAHs that were IPPS hospitals for the time period of the MedPAR data being used to calculate the charge inflation factor; include hospitals in Maryland; and remove PPS excluded cancer hospitals who have a "V" in the fifth position of their provider number or a "E" or "F" in the sixth position.
- We excluded Medicare Advantage IME claims for the reasons described in section I.A.4. of this Addendum. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.
- In order to ensure that we capture only FFS claims, we included claims with a "Claim Type" of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).
- In order to further ensure that we capture only FFS claims, we excluded claims with a "GHOPAID" indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).
- We examined the MedPAR file and removed pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of "3" for blood clotting with a revenue code of "0636" from the covered charge field. We also removed organ acquisition charges from the covered charge field because organ acquisition is a pass-through payment not paid under the IPPS.

In the FY 2016 IPPS/LTCH final rule (80 FR 49779–49780), we stated that commenters were concerned that they were unable to replicate the calculation of the charge inflation factor that CMS used in the proposed rule. In response to those comments, we stated that we continue to believe that it is optimal to use the most recent period of charge data available to measure charge inflation. In response to those comments, similar to FY 2016, for FY 2017 we grouped claims data by quarter in the table below in order that the public would be able to replicate the claims summary for the claims with discharge dates through September 30, 2015, that are available under the current LDS structure. In order to provide even more information in response to the commenters' request, similar to FY 2016, for FY 2017 we have made available on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* (click on the link on the left titled "FY 2017 IPPS Proposed Rule Home Page"' and then click the link "FY 2017 Proposed Rule Data Files"') a more detailed summary table by provider with the monthly charges that were used to compute the charge inflation factor. We continue to work with our systems teams and privacy office to explore expanding the information available in the current LDS, perhaps through the provision of a supplemental data file for future rulemaking.

Quarter	Covered charges (January 1, 2014, through December 31, 2014)	Cases (January 1, 2014, through December 31, 2014)	Covered charges (January 1, 2015, through December 31, 2015)	Cases (January 1, 2015, through December 31, 2015)
1	$126,156,195,005	2,479,295	$134,250,323,661	2,546,078
2	122,171,248,575	2,445,370	126,880,227,174	2,416,569
3	119,364,629,662	2,364,553	122,165,668,615	2,308,537
4	124,733,843,923	2,436,787	90,677,073,204	1,696,180
Total	492,425,917,165	9,726,005	473,973,292,654	8,967,364

Under this methodology, to compute the 1-year average annualized rate-of-change in charges per case for FY 2017, we are proposing to compare the average covered charge per case of $50,360 ($492,425,917,165/9,726,005) from the second quarter of FY 2014 through the first quarter of FY 2015 (January 1, 2014, through December 31, 2014) to the average covered charge per case of $52,855 ($473,973,292,654/8,967,364) from the second quarter of FY 2015 through the first quarter of FY 2016 (January 1, 2015, through December 31, 2015). This rate-of-change is 4.4 percent (1.043957) or 9.8 percent (1.089846) over 2 years. The billed charges are obtained from the claim from the MedPAR file and inflated by the inflation factor specified above.

As we have done in the past, in this proposed rule, we are proposing to establish the proposed FY 2017 outlier threshold using hospital CCRs from the December 2015 update to the Provider-Specific File (PSF)—

the most recent available data at the time of the development of this proposed rule. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we apply the following edits to providers' CCRs in the PSF. We believe these edits are appropriate in order to accurately model the outlier threshold. We first search for Indian Health Service providers and those providers assigned the statewide average CCR from the current fiscal year. We then replace these CCRs with the statewide average CCR for the upcoming fiscal year. We also assign the statewide average CCR (for the upcoming fiscal year) to those providers that have no value in the CCR field in the PSF. We do not apply the adjustment factors described below to hospitals assigned the statewide average CCR.

For FY 2017, we also are proposing to continue to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained below). We are proposing that, if more recent data become available, we would use that data to calculate the final FY 2017 outlier threshold.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we adopted a new methodology to adjust the CCRs. Specifically, we finalized a policy to compare the national average case-weighted operating and capital CCR from the most recent update of the PSF to the national average case-weighted operating and capital CCR from the same period of the prior year.

Therefore, as we did for the last 3 fiscal years, we are proposing to adjust the CCRs from the December 2015 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the December 2014 update of the PSF to the national average case-weighted operating CCR and capital CCR from the December 2015 update of the PSF. We note that we used total transfer-adjusted cases from FY 2015 to determine the national average case-weighted CCRs for both sides of the comparison. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we believe that it is appropriate to use the same case count on both sides of the comparison because this will produce the true percentage change in the average case-weighted operating and capital CCR from one year to the next without any effect from a change in case count on different sides of the comparison.

Using the proposed methodology above, we calculated a proposed December 2014 operating national average case-weighted CCR of 0.280907 and a proposed December 2015 operating national average case-weighted CCR of 0.272363. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the December 2014 operating national average case-weighted CCR from the December 2015 operating national average case-weighted CCR and then dividing the result by the December 2014 national operating average case-weighted CCR. This resulted in a proposed national operating CCR adjustment factor of 0.969585.

We used the same methodology proposed above to adjust the capital CCRs. Specifically, we calculated a December 2014 capital national average case-weighted CCR of 0.024615 and a December 2015 capital national average case-weighted CCR of 0.024008. We then calculated the percentage change between the two national capital case-weighted CCRs by subtracting the December 2014 capital national average case-weighted CCR from the December 2015 capital national average case-weighted CCR and then dividing the result by the December 2014 capital national average case-weighted CCR. This resulted in a proposed national capital CCR adjustment factor of 0.975335.

As discussed above, for FY 2017, we are proposing to apply the final year of the 3-year transitional wage index because of the adoption of the new OMB labor market area delineations. Also, as discussed in section III.B.3. of the preamble to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 and 50161) and in section III.H.3. of the preamble of this proposed rule, in accordance with section 10324(a) of the Affordable Care Act, we created a wage index floor of 1.0000 for all hospitals located in States determined to be frontier States. We note that the frontier State floor adjustments would be calculated and applied after rural and imputed floor budget neutrality adjustments are calculated for all labor market areas, in order to ensure that no hospital in a frontier State would receive a wage index less than 1.0000 due to the proposed rural and imputed floor adjustment. In accordance with section 10324(a) of the Affordable Care Act, the frontier State adjustment will not be subject to budget neutrality, and will only be extended to hospitals geographically located within a frontier State. However, for purposes of estimating the proposed outlier threshold for FY 2017, it was necessary to apply the proposed 3-year transitional wage indexes and adjust the proposed wage index of those eligible hospitals in a frontier State when calculating the proposed outlier threshold that results in outlier payments being 5.1 percent of total payments for FY 2017. If we did not take the above into account, our estimate of total FY 2017 payments would be too low, and, as a result, our proposed outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.1 percent of total payments.

As we did in establishing the FY 2009 outlier threshold (73 FR 57891), in our projection of FY 2017 outlier payments, we are proposing not to make any adjustments for the possibility that hospitals' CCRs and outlier payments may be reconciled upon cost report settlement. We continue to believe that, due to the policy implemented in the June 9, 2003 Outlier Final Rule (68 FR 34494), CCRs will no longer fluctuate significantly and, therefore, few hospitals will actually have these ratios reconciled upon cost report settlement. In addition, it is difficult to predict the specific hospitals that will have CCRs and outlier payments reconciled in any given year. We note that we have instructed MACs to identify for CMS any instances where (1) a hospital's actual CCR for the cost reporting period fluctuates plus or minus 10 percentage points compared to the interim CCR used to calculate outlier payments when a bill is processed; and (2) the total outlier payments for the hospital exceeded $500,000.00 for that period. Our simulations assume that CCRs accurately measure hospital costs based on information available to us at the time we set the outlier threshold. For these reasons, we are proposing not to make any assumptions regarding the effects of reconciliation on the outlier threshold calculation.

As described in sections IV.G. and IV.H. respectively, of the preamble of this proposed rule, sections 1886(q) and 1886(o) of the Act establish the Hospital Readmissions Reduction Program and the Hospital VBP Program, respectively. We do not believe that it is appropriate to include the hospital VBP payment adjustments and the hospital readmissions payment adjustments in the proposed outlier threshold calculation or the proposed outlier offset to the standardized amount. Specifically, consistent with our definition of the base operating DRG payment amount for the Hospital Readmissions Reduction Program under § 412.152 and the Hospital VBP Program under § 412.160, outlier payments under section 1886(d)(5)(A) of the Act are not affected by these payment adjustments. Therefore, outlier payments would continue to be calculated based on the unadjusted base DRG payment amount (as opposed to using the base-operating DRG payment amount adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment). Consequently, we are proposing to exclude the hospital VBP payment adjustments and the hospital readmissions payment adjustments from the calculation of the proposed outlier fixed-loss cost threshold.

We note that, to the extent section 1886(r) of the Act modifies the DSH payment methodology under section 1886(d)(5)(F) of the Act, the new uncompensated care payment under section 1886(r)(2) of the Act, like the empirically justified Medicare DSH payment under section 1886(r)(1) of the Act, may be considered an amount payable under section 1886(d)(5)(F) of the Act such that it would be reasonable to include the payment in the outlier determination under section 1886(d)(5)(A) of the Act. As we have done since the implementation of uncompensated care payments in FY 2014, we also are proposing for FY 2017 to allocate an estimated per-discharge uncompensated care payment amount to all cases for the hospitals eligible to receive the uncompensated care payment amount in the calculation of the outlier fixed-loss cost threshold methodology. We continue to believe that allocating an eligible hospital's estimated uncompensated care payment to all cases equally in the calculation of the outlier fixed-loss cost threshold would best approximate the amount we would pay in uncompensated care payments during the year because, when we make claim payments to a hospital eligible for such payments, we would be making estimated per-discharge uncompensated care payments to all cases equally. Furthermore, we continue to believe that using the estimated per-claim uncompensated care payment amount to determine outlier estimates provides predictability as to the amount of uncompensated care payments included in the calculation of outlier payments. Therefore, consistent with the methodology used since FY 2014 to calculate the outlier fixed-loss cost threshold, for FY 2017, we are proposing to include estimated FY 2017 uncompensated care payments in the computation of the proposed outlier fixed-loss cost threshold. Specifically, we are proposing to use the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the proposed outlier fixed-loss cost threshold methodology.

Using this methodology, we used the formula described in section I.C.1 of this Addendum to simulate and calculate the Federal payment rate and outlier payments for all claims. We used a threshold of $23,681 and calculated total operating Federal payments of $82,727,323,366 and total outlier payments of $4,445,892,903. We then divided total outlier payments by total operating Federal payments plus total outlier payments and determined that this threshold met the 5.1 percent target. As a result, we are proposing an outlier fixed-loss cost threshold for FY 2017 equal to the prospective payment rate for the MS–DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, and any add-on payments for new technology, plus $23,681.

(2) Other Proposed Changes Concerning Outliers

As stated in the FY 1994 IPPS final rule (58 FR 46348), we establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. When we modeled the combined operating and capital outlier payments, we found that using a common threshold resulted in a lower percentage of outlier payments for capital-related costs than for operating costs. We project that the thresholds for FY 2017 will result in outlier payments that will equal 5.1 percent of operating DRG payments and 6.26 percent of capital payments based on the Federal rate.

In accordance with section 1886(d)(3)(B) of the Act, we are proposing to reduce the FY 2017 standardized amount by the same percentage to account for the projected proportion of payments paid as outliers.

The proposed outlier adjustment factors that would be applied to the standardized amount based on the proposed FY 2017 outlier threshold are as follows:

	Operating standardized amounts	Capital Federal rate
National	0.948999	0.937400

We are proposing to apply the outlier adjustment factors to the proposed FY 2017 payment rates after removing the effects of the FY 2016 outlier adjustment factors on the standardized amount.

To determine whether a case qualifies for outlier payments, we apply hospital-specific CCRs to the total covered charges for the case. Estimated operating and capital costs for the case are calculated separately by applying separate operating and capital CCRs. These costs are then combined and compared with the outlier fixed-loss cost threshold.

Under our current policy at § 412.84, we calculate operating and capital CCR ceilings and assign a statewide average CCR for hospitals whose CCRs exceed 3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals. Based on this calculation, for hospitals for which the MAC computes operating CCRs greater than 1.19 or capital CCRs greater than 0.171, or hospitals for which the MAC is unable to calculate a CCR (as described under § 412.84(i)(3) of our regulations), statewide average CCRs are used to determine whether a hospital qualifies for outlier payments. Table 8A listed in section VI. of this Addendum (and available only via the Internet on the CMS Web site) contains the proposed statewide average operating CCRs for urban hospitals and for rural hospitals for which the MAC is unable to compute a hospital-specific CCR within the above range. Effective for discharges occurring on or after October 1, 2016, these statewide average ratios would replace the ratios posted on our Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY-2014-IPPS-Final-Rule-Home-Page-Items/FY-2014-IPPS-Final-Rule-CMS-1599-F-Tables.html*. Table 8B listed in section VI. of this Addendum (and available via the Internet on the CMS Web site) contains the comparable proposed statewide average capital CCRs. As previously stated, the proposed CCRs in Tables 8A and 8B would be used during FY 2017 when hospital-specific CCRs based on the latest settled cost report either are not available or are outside the range noted above. Table 8C listed in section VI. of this Addendum (and available via the Internet on the CMS Web site) contains the proposed statewide average total CCRs used under the LTCH PPS as discussed in section V. of this Addendum.

We finally note that we published a manual update (Change Request 3966) to our outlier policy on October 12, 2005, which updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update covered an array of topics, including CCRs, reconciliation, and the time value of money. We encourage hospitals that are assigned the statewide average operating and/or capital CCRs to work with their MAC on a possible alternative operating and/or capital CCR as explained in Change Request 3966. Use of an alternative CCR developed by the hospital in conjunction with the MAC can avoid possible overpayments or underpayments at cost report settlement, thereby ensuring better accuracy when making outlier payments and negating the need for outlier reconciliation. We also note that a hospital may request an alternative operating or capital CCR ratio at any time as long as the guidelines of Change Request 3966 are followed. In addition, as mentioned above, we published an additional manual update (Change Request 7192) to our outlier policy on December 3, 2010, which also updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update outlines the outlier reconciliation process for hospitals and Medicare contractors. To download and view the manual instructions on outlier reconciliation, we refer readers to the CMS Web site: *http://www.cms.hhs.gov/manuals/downloads/clm104c03.pdf*.

(3) FY 2015 Outlier Payments

Our current estimate, using available FY 2015 claims data, is that actual outlier payments for FY 2015 were approximately 4.68 percent of actual total MS–DRG payments. Therefore, the data indicate that, for FY 2015, the percentage of actual outlier payments relative to actual total payments is lower than we projected for FY 2015. Consistent with the policy and statutory interpretation we have maintained since the inception of the IPPS, we do not make retroactive adjustments to outlier payments to ensure that total outlier payments for FY 2015 are equal to 5.1 percent of total MS–DRG payments. As explained in the FY 2003 Outlier Final Rule (68 FR 34502), if we were to make retroactive adjustments to all outlier payments to ensure total payments are 5.1 percent of MS–DRG payments (by retroactively adjusting outlier payments), we would be removing the important aspect of the prospective nature of the IPPS. Because such an across-the-board adjustment would either lead to more or less outlier payments for all hospitals, hospitals would no longer be able to reliably approximate their payment for a patient while the patient is still hospitalized. We believe it would be neither necessary nor appropriate to make such an aggregate retroactive adjustment. Furthermore, we believe it is consistent with the intent of the language at section 1886(d)(5)(A)(iv) of the Act not to make retroactive adjustments to outlier payments. This section calls for the Secretary to ensure that outlier payments are equal to or greater than 5 percent and less than or equal to 6 percent of projected or estimated (not actual) MS–DRG payments. We believe this language reflects the intent of Congress regarding the prospectivity of the IPPS. We believe that an important goal of a PPS is predictability. Therefore, we believe that the fixed-loss outlier threshold should be projected based on the best available historical data and should not be adjusted retroactively. A retroactive change to the fixed-loss outlier threshold would affect all hospitals subject to the IPPS, thereby undercutting the predictability of the system as a whole.

We note that because the MedPAR claims data for the entire FY 2016 will not be available until after September 30, 2016, we are unable to provide an estimate of actual outlier payments for FY 2016 based on FY 2016 claims data in this proposed rule. We will provide an estimate of actual FY 2016 outlier payments in the FY 2018 IPPS/LTCH PPS proposed rule.

5. Proposed FY 2017 Standardized Amount

The adjusted standardized amount is divided into labor-related and nonlabor-related portions. Tables 1A and 1B listed and published in section VI. of this Addendum (and available via the Internet on the CMS Web site) contain the national standardized amounts that we are proposing to apply to all hospitals, except hospitals located in Puerto

Rico, for FY 2017. The proposed standardized amount for hospitals in Puerto Rico is shown in Table 1C listed and published in section VI. of this Addendum (and available via the Internet on the CMS Web site). The proposed amounts shown in Tables 1A and 1B differ only in that the labor-related share applied to the standardized amounts in Table 1A is 69.6 percent, and the labor-related share applied to the standardized amounts in Table 1B is 62 percent. In accordance with sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act, we are proposing to apply a labor-related share of 62 percent, unless application of that percentage would result in lower payments to a hospital than would otherwise be made. In effect, the statutory provision means that we will apply a labor-related share of 62 percent for all hospitals whose wage indexes are less than or equal to 1.0000.

In addition, Tables 1A and 1B include the proposed standardized amounts reflecting the proposed applicable percentage increases for FY 2017.

The proposed labor-related and nonlabor-related portions of the national average standardized amounts for Puerto Rico hospitals for FY 2017 are set forth in Table 1C listed and published in section VI. of this Addendum (and available via the Internet on the CMS Web site). Similar to above, section 1886(d)(9)(C)(iv) of the Act, as amended by section 403(b) of Public Law 108–173, provides that the labor-related share for hospitals located in Puerto Rico be 62 percent, unless the application of that percentage would result in lower payments to the hospital.

The following table illustrates the changes from the FY 2016 national standardized amount to the proposed FY 2017 national standardized amount. The second through fifth columns display the proposed changes from the FY 2016 standardized amounts for each applicable FY 2017 standardized amount. The first row of the table shows the updated (through FY 2016) average standardized amount after restoring the FY 2016 offsets for outlier payments, demonstration budget neutrality, geographic reclassification budget neutrality, new labor market delineation wage index transition budget neutrality, retrospective documentation and coding adjustment under section 7(b)(1)(B) of Public Law 110–90 and an adjustment to the standardized amount using our authority under section 1886(d)(5)(I)(i) of the Act to permanently prospectively remove the 0.2 percent reduction to the rate put in place in FY 2014 to offset the estimated increase in IPPS expenditures as a result of the 2-midnight policy . The MS–DRG reclassification and recalibration and wage index budget neutrality adjustment factors are cumulative. Therefore, those FY 2016 adjustment factors are not removed from this table.

COMPARISON OF FY 2016 STANDARDIZED AMOUNTS TO THE PROPOSED FY 2017 STANDARDIZED AMOUNTS

	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
FY 2016 Base Rate after removing: 1. FY 2016 Geographic Reclassification Budget Neutrality (0.988169). 2. FY 2016 Rural Community Hospital Demonstration Program Budget Neutrality (0.999837). 3. Cumulative FY 2008, FY 2009, FY 2012, FY 2013, FY 2014, FY 2015 and FY 2016 Documentation and Coding Adjustments as Required under Sections 7(b)(1)(A) and 7(b)(1)(B) of Pub. L. 110–90 and Documentation and Coding Recoupment Adjustment as required under Section 631 of the American Taxpayer Relief Act of 2012 (0.9255). 4. FY 2016 Operating Outlier Offset (0.948998). 5. FY 2016 New Labor Market Delineation Wage Index Transition Budget Neutrality Factor (0.999998). 6. FY 2017 Proposed 2-Midnight Rule Permanent Adjustment (1/0.998).	If Wage Index is Greater Than 1.0000: Labor (69.6%): $4,394.09. Nonlabor (30.4%): $1,919.26. If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,914.28. Nonlabor (38%): $2,399.07.	If Wage Index is Greater Than 1.0000: Labor (69.6%): $4,394.09. Nonlabor (30.4%): $1,919.26. If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,914.28. Nonlabor (38%): $2,399.07.	If Wage Index is Greater Than 1.0000: Labor (69.6%): $4,394.09. Nonlabor (30.4%): $1,919.26. If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,914.28. Nonlabor (38%): $2,399.07.	If Wage Index is Greater Than 1.0000: Labor (69.6%): $4,394.09 Nonlabor (30.4%): $1,919.26 If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,914.28 Nonlabor (38%): $2,399.07
Proposed FY 2017 Update Factor	1.0155	0.9945	1.0085	0.9875
Proposed FY 2017 MS–DRG Recalibration Budget Neutrality Factor.	0.999006	0.999006	0.999006	0.999006
Proposed FY 2017 Wage Index Budget Neutrality Factor.	0.999785	0.999785	0.999785	0.999785
Proposed FY 2017 Reclassification Budget Neutrality Factor.	0.988816	0.988816	0.988816	0.988816
Proposed FY 2017 Operating Outlier Factor	0.948999	0.948999	0.948999	0.98999

COMPARISON OF FY 2016 STANDARDIZED AMOUNTS TO THE PROPOSED FY 2017 STANDARDIZED AMOUNTS—Continued

	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Cumulative Factor: FY 2008, FY 2009, FY 2012, FY 2013, FY 2014, FY 2015, FY 2016 and FY 2017 Documentation and Coding Adjustment as Required under Sections 7(b)(1)(A) and 7(b)(1)(B) of Pub. L. 110–90 and Documentation and Coding Recoupment Adjustment as required under Section 631 of the American Taxpayer Relief Act of 2012.	0.9118	0.9118	0.9118	0.9118
Proposed FY 2017 New Labor Market Delineation Wage Index 3-Year Hold Harmless Transition Budget Neutrality Factor.	0.999999	0.999999	0.999999	0.999999
Proposed FY 2017 2-Midnight Rule One-Time Prospective Increase.	1.006	1.006	1.006	1.006
Proposed National Standardized Amount for FY 2017 if Wage Index is Greater Than 1.0000; Labor/Non-Labor Share Percentage (69.6/30.4).	Labor: $3,836.20 Nonlabor: $1,675.59	Labor: $3,756.87 Nonlabor: $1,640.94	Labor: $3,809.76 Nonlabor: $1,664.04	Labor: $3,730.43 Nonlabor: $1,629.39
Proposed National Standardized Amount for FY 2017 if Wage Index is less Than or Equal to 1.0000; Labor/Non-Labor Share Percentage (62/38).	Labor: $3,417.31 Nonlabor: $2,094.48	Labor: $3,346.64 Nonlabor: $2,051.17	Labor: $3,393.76 Nonlabor: $2,080.04	Labor: $3,323.09 Nonlabor: $2,036.73

B. Proposed Adjustments for Area Wage Levels and Cost-of-Living

Tables 1A through 1C, as published in section VI. of this Addendum (and available via the Internet on the CMS Web site), contain the proposed labor-related and nonlabor-related shares that we are proposing to use to calculate the prospective payment rates for hospitals located in the 50 States, the District of Columbia, and Puerto Rico for FY 2017. This section addresses two types of adjustments to the standardized amounts that are made in determining the proposed prospective payment rates as described in this Addendum.

1. Proposed Adjustment for Area Wage Levels

Sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act require that we make an adjustment to the labor-related portion of the national prospective payment rate to account for area differences in hospital wage levels. This adjustment is made by multiplying the labor-related portion of the adjusted standardized amounts by the appropriate wage index for the area in which the hospital is located. In section III. of the preamble of this proposed rule, we discuss the data and methodology for the proposed FY 2017 wage index.

2. Adjustment for Cost-of-Living in Alaska and Hawaii

Section 1886(d)(5)(H) of the Act provides discretionary authority to the Secretary to make such adjustments as the Secretary deems appropriate to take into account the unique circumstances of hospitals located in Alaska and Hawaii. Higher labor-related costs for these two States are taken into account in the adjustment for area wages described above. To account for higher nonlabor-related costs for these two States, we multiply the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii by an adjustment factor.

In the FY 2013 IPPS/LTCH PPS final rule, we established a methodology to update the COLA factors for Alaska and Hawaii that were published by the U.S. Office of Personnel Management (OPM) every 4 years (at the same time as the update to the labor-related share of the IPPS market basket), beginning in FY 2014. We refer readers to the FY 2013 IPPS/LTCH PPS proposed and final rules for additional background and a detailed description of this methodology (77 FR 28145 through 28146 and 77 FR 53700 through 53701, respectively).

For FY 2014, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50985 through 50987), we updated the COLA factors published by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule.

Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, we are proposing to continue to use the same COLA factors in FY 2017 that were used in FY 2016 to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii. Below is a table listing the proposed COLA factors for FY 2017.

PROPOSED FY 2017 COST-OF-LIVING ADJUSTMENT FACTORS: ALASKA AND HAWAII HOSPITALS

Area	Cost of living adjustment factor
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.23
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.23
City of Juneau and 80-kilometer (50-mile) radius by road	1.23
Rest of Alaska	1.25
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.19
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, the next update to the COLA factors for Alaska and Hawaii would occur in FY 2018.

C. Calculation of the Proposed Prospective Payment Rates

General Formula for Calculation of the Prospective Payment Rates for FY 2017

In general, the operating prospective payment rate for all hospitals (including hospitals in Puerto Rico) paid under the IPPS, except SCHs and MDHs, for FY 2017 equals the Federal rate (which includes uncompensated care payments).

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal national rate (which, as discussed in section IV.F. of the preamble of this proposed rule, includes uncompensated care payments); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

The prospective payment rate for SCHs for FY 2017 equals the higher of the applicable Federal rate, or the hospital-specific rate as described below. The prospective payment rate for MDHs for FY 2017 equals the higher of the Federal rate, or the Federal rate plus 75 percent of the difference between the Federal rate and the hospital-specific rate as described below. For MDHs, the updated hospital-specific rate is based on FY 1982, FY 1987 or FY 2002 costs per discharge, whichever yields the greatest aggregate payment.

1. Operating and Capital Federal Payment Rate and Outlier Payment Calculation

Note: The formula below is used for actual claim payment and is also used by CMS to project the outlier threshold for the upcoming FY. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the PSF while CMS uses an adjusted CCR (as described above) to project the threshold for the upcoming FY. In addition, charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described above).

Step 1—Determine the MS–DRG and MS–DRG relative weight for each claim based on the ICD–10–CM procedure and diagnosis codes on the claim.

Step 2—Select the applicable average standardized amount depending on whether the hospital submitted qualifying quality data and is a meaningful EHR user, as described above.

Step 3—Compute the operating and capital Federal payment rate:

—Federal Payment Rate for Operating Costs = MS–DRG Relative Weight × [(Labor-Related Applicable Standardized Amount × Applicable CBSA Wage Index) + (Nonlabor-Related Applicable Standardized Amount × Cost of Living Adjustment)] × (1 + IME + (DSH * 0.25))

—Federal Payment for Capital Costs = MS–DRG Relative Weight × Federal Capital Rate × Geographic Adjustment Fact × (1 + IME + DSH)

Step 4—Determine operating and capital costs:

—Operating Costs = (Billed Charges × Operating cost-to-charge ratio)

—Capital Costs = (Billed Charges × Capital cost-to-charge ratio).

Step 5—Compute operating and capital outlier threshold (CMS applies a geographic adjustment to the operating and capital outlier threshold to account for local cost variation):

—Operating Cost-to-Charge Ratio to Total Cost-to-Charge Ratio = (Operating Cost-to-Charge Ratio)/(Operating Cost-to-Charge Ratio + Capital Cost-to-Charge Ratio)

—Operating Outlier Threshold = [Fixed Loss Threshold × ((Labor-Related Portion × CBSA Wage Index) + Nonlabor-Related portion)] × Operating Cost-to-Charge Ratio to Total Cost-to-Charge Ratio + Federal Payment with IME, DSH + Uncompensated Care Payment + New Technology Add-On Payment Amount

—Capital Cost-to-Charge Ratio to Total Cost-to-Charge Ratio = (Capital Cost-to-Charge Ratio)/(Operating Cost-to-Charge Ratio + Capital Cost-to-Charge Ratio)

—Capital Outlier Threshold = (Fixed Loss Threshold × Geographic Adjustment Factor × Capital CCR to Total CCR) + Federal Payment with IME and DSH

Step 6: Compute operating and capital outlier payments:

—Marginal Cost Factor = 0.80 or 0.90 (depending on the MS–DRG)

—Operating Outlier Payment = (Operating Costs—Operating Outlier Threshold) × Marginal Cost Factor

—Capital Outlier Payment = (Capital Costs—Capital Outlier Threshold) × Marginal Cost Factor

The payment rate may then be further adjusted for hospitals that qualify for a low-volume payment adjustment under section 1886(d)(12) of the Act and 42 CFR 412.101(b). The base-operating DRG payment amount may be further adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment as described under sections 1886(q) and 1886(o) of the Act, respectively. Payments also may be reduced by the 1-percent adjustment under the HAC Reduction Program as described in section 1886(p) of the Act. We also make new technology add-on payments in accordance with section 1886(d)(5)(K) and (L) of the Act. Finally, we add the uncompensated care payment to the total claim payment amount. As noted in the formula above, we take uncompensated care payments and new technology add-on payments into consideration when calculating outlier payments.

2. Hospital-Specific Rate (Applicable Only to SCHs and MDHs)

a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

As noted above, section 205 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) extended the MDH program through FY 2017 (that is, for discharges occurring on or before September 30, 2017). Currently MDHs are paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the greater of the updated hospital-specific rates based on either FY 1982, FY 1987 or FY 2002 costs per discharge.

For a more detailed discussion of the calculation of the hospital-specific rates, we refer readers to the FY 1984 IPPS interim final rule (48 FR 39772); the April 20, 1990 final rule with comment period (55 FR 15150); the FY 1991 IPPS final rule (55 FR 35994); and the FY 2001 IPPS final rule (65 FR 47082).

b. Updating the FY 1982, FY 1987, FY 1996, FY 2002 and FY 2006 Hospital-Specific Rate for FY 2017

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Because the Act sets the update factor for SCHs and MDHs equal to the update factor for all other IPPS hospitals, the update to the hospital-specific rates for SCHs and MDHs is subject to the amendments to section 1886(b)(3)(B) of the Act made by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, the proposed applicable percentage increases to the hospital-specific rates applicable to SCHs and MDHs are the following:

FY 2017	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Proposed Market Basket Rate-of-Increase	2.8	2.8	2.8	2.8
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.7	−0.7
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−2.1	0.0	−2.1
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.5	−0.5	−0.5	−0.5
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.75	−0.75	−0.75	−0.75
Proposed Applicable Percentage Increase Applied to Hospital-Specific Rate	1.55	−0.55	0.85	−1.25

For a complete discussion of the applicable percentage increase applied to the hospital-specific rates for SCHs and MDHs, we refer readers to section IV.B. of the preamble of this proposed rule.

In addition, because SCHs and MDHs use the same MS–DRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, the hospital-specific rate is adjusted by a budget neutrality factor to ensure that changes to the MS–DRG classifications and the recalibration of the MS–DRG relative weights are made in a manner so that aggregate IPPS payments are unaffected. Therefore, the hospital-specific rate for an SCH or an MDH is adjusted by the proposed MS–DRG reclassification and recalibration budget neutrality factor of 0.999006, as discussed in section III. of this Addendum. The resulting rate is used in determining the payment rate that an SCH or MDH will receive for its discharges beginning on or after October 1, 2016. We note that, in this proposed rule, for FY 2017, we are not proposing to make a documentation and coding adjustment to the hospital-specific rate. We refer readers to section II.D. of the preamble of this proposed rule for a complete discussion regarding our proposed policies and previously finalized policies (including our historical adjustments to the payment rates) relating to the effect of changes in documentation and coding that do not reflect real changes in case-mix. Also, as discussed above and in section IV.O. of the preamble of this proposed rule, we are proposing an adjustment to the hospital-specific rates using our authority under section 1886(d)(5)(I)(i) of the Act to permanently prospectively remove the 0.2 percent reduction to the rates put in place in FY 2014 to offset the estimated increase in IPPS expenditures as a result of the 2-midnight policy. In addition, as discussed above and in section IV.O. of the preamble of this proposed rule, we are proposing a temporary one-time prospective increase to the FY 2017 hospital-specific rates of 0.6 percent by including a temporary one-time factor of 1.006 in the calculation of the hospital-specific rates, using our authority under section 1886(d)(5)(I)(i) of the Act, to address the effects of the 0.2 percent reduction to the rates for the 2-midnight policy in effect for FY 2014, FY 2015, and FY 2016.

III. Proposed Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2017

The PPS for acute care hospital inpatient capital-related costs was implemented for cost reporting periods beginning on or after October 1, 1991. Effective with that cost reporting period, over a 10-year transition period (which extended through FY 2001) the payment methodology for Medicare acute care hospital inpatient capital-related costs changed from a reasonable cost-based methodology to a prospective methodology (based fully on the Federal rate).

The basic methodology for determining Federal capital prospective rates is set forth in the regulations at §§ 412.308 through 412.352. In this section, we discuss the factors that we used to determine the proposed capital Federal rate for FY 2017, which would be effective for discharges occurring on or after October 1, 2016.

The 10-year transition period ended with hospital cost reporting periods beginning on or after October 1, 2001 (FY 2002). Therefore, for cost reporting periods beginning in FY 2002, all hospitals (except "new" hospitals under § 412.304(c)(2)) are paid based on the capital Federal rate. For FY 1992, we computed the standard Federal payment rate for capital-related costs under the IPPS by updating the FY 1989 Medicare inpatient capital cost per case by an actuarial estimate of the increase in Medicare inpatient capital costs per case. Each year after FY 1992, we update the capital standard Federal rate, as provided at § 412.308(c)(1), to account for capital input price increases and other factors. The regulations at § 412.308(c)(2) also provide that the capital Federal rate be adjusted annually by a factor equal to the estimated proportion of outlier payments under the capital Federal rate to total capital payments under the capital Federal rate. In addition, § 412.308(c)(3) requires that the capital Federal rate be reduced by an adjustment factor equal to the estimated proportion of payments for exceptions under § 412.348. (We note that, as discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53705), there is generally no longer a need for an exceptions payment adjustment factor.) However, in limited circumstances, an additional payment exception for extraordinary circumstances is provided for under § 412.348(f) for qualifying hospitals. Therefore, in accordance with § 412.308(c)(3), an exceptions payment adjustment factor may need to be applied if such payments are made. Section 412.308(c)(4)(ii) requires that the capital standard Federal rate be adjusted so that the effects of the annual DRG reclassification and the recalibration of DRG weights and changes in the geographic adjustment factor (GAF) are budget neutral.

Section 412.374 provides for blended payments to hospitals located in Puerto Rico under the IPPS for acute care hospital inpatient capital-related costs. Accordingly, historically, under the capital PPS, we have computed a separate payment rate specific to hospitals located in Puerto Rico using the same methodology used to compute the national Federal rate for capital-related costs. Effective with discharges occurring on or after October 1, 2004, in conjunction with the change to the operating payment methodology, we adopted a methodology for computing capital payments made to hospitals located in Puerto Rico based on a blend of 25 percent of the Puerto Rico capital rate and 75 percent of the national capital Federal rate (69 FR 49185). Effective with discharges on or after January 1, 2016, operating IPPS payments to hospitals located in Puerto Rico are now based on 100 percent of the Federal rate—the operating payment methodology is no longer a blend of 75 percent of the Federal rate and 25 percent of the Puerto Rico rate. Consistent with historical practice and under the authority of section 1886(g) of the Act, as discussed in section V.B.3. of the preamble of this proposed rule, we are proposing that the capital IPPS payments to hospitals located in Puerto Rico would be based on 100 percent of the capital Federal rate, effective with discharges on or after October 1, 2016, and would no longer be based on the current 75/25 blended rate.

A. Determination of the Proposed Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update

In the discussion that follows, we explain the factors that we used to determine the proposed capital Federal rate for FY 2017. In particular, we explain why the proposed FY 2017 capital Federal rate increases approximately 1.7 percent, compared to the FY 2016 capital Federal rate. As discussed in the impact analysis in Appendix A to this proposed rule, we estimate that capital payments per discharge will increase approximately 2.0 percent during that same period. Because capital payments constitute approximately 10 percent of hospital payments, a percent change in the capital Federal rate yields only approximately a 0.1 percent change in actual payments to hospitals.

1. Projected Capital Standard Federal Rate Update

a. Description of the Update Framework

Under § 412.308(c)(1), the capital standard Federal rate is updated on the basis of an analytical framework that takes into account changes in a capital input price index (CIPI) and several other policy adjustment factors. Specifically, we adjust the projected CIPI rate-of-increase as appropriate each year for case-mix index-related changes, for intensity, and for errors in previous CIPI forecasts. The proposed update factor for FY 2017 under that framework is 0.9 percent based on the best data available at the time of development of this proposed rule. The proposed update factor under that framework is based on a projected 1.2 percent increase in the FY 2010-based CIPI, a 0.0 percentage point adjustment for intensity, a 0.0 percentage point adjustment for case-mix, a 0.0 percentage point adjustment for the DRG reclassification and recalibration, and a forecast error correction of -0.3 percentage point. As discussed in section III.C. of this Addendum, we continue to believe that the CIPI is the most appropriate input price index for capital costs to measure capital price changes in a given year. We also explain the basis for the FY 2017 CIPI projection in that same section of this Addendum. Below we describe the policy adjustments that we are proposing to apply in the update framework for FY 2017.

The case-mix index is the measure of the average DRG weight for cases paid under the IPPS. Because the DRG weight determines the prospective payment for each case, any percentage increase in the case-mix index corresponds to an equal percentage increase in hospital payments.

The case-mix index can change for any of several reasons:

- The average resource use of Medicare patient changes ("real" case-mix change);
- Changes in hospital documentation and coding of patient records result in higher-weighted DRG assignments ("coding effects"); and
- The annual DRG reclassification and recalibration changes may not be budget neutral ("reclassification effect").

We define real case-mix change as actual changes in the mix (and resource requirements) of Medicare patients as opposed to changes in documentation and coding behavior that result in assignment of cases to higher-weighted DRGs, but do not reflect higher resource requirements. The capital update framework includes the same case-mix index adjustment used in the former operating IPPS update framework (as discussed in the May 18, 2004 IPPS proposed rule for FY 2005 (69 FR 28816)). (We no longer use an update framework to make a recommendation for updating the operating IPPS standardized amounts as discussed in section II. of Appendix B to the FY 2006 IPPS final rule (70 FR 47707).)

For FY 2017, we are projecting a 0.5 percent total increase in the case-mix index. We estimated that the real case-mix increase will equal 0.5 percent for FY 2017. The net adjustment for change in case-mix is the difference between the projected real increase in case-mix and the projected total increase in case-mix. Therefore, we are proposing the net adjustment for case-mix change in FY 2017 of 0.0 percentage point.

The capital update framework also contains an adjustment for the effects of DRG reclassification and recalibration. This adjustment is intended to remove the effect on total payments of prior year's changes to the DRG classifications and relative weights, in order to retain budget neutrality for all case-mix index-related changes other than those due to patient severity of illness. Due to the lag time in the availability of data, there is a 2-year lag in data used to determine the adjustment for the effects of DRG reclassification and recalibration. For example, we have data available to evaluate the effects of the FY 2015 DRG reclassification and recalibration as part of our update for FY 2017. We estimate that FY 2015 DRG reclassification and recalibration resulted in no change in the case-mix when compared with the case-mix index that would have resulted if we had not made the reclassification and recalibration changes to the DRGs. Therefore, we are proposing a 0.0 percentage point adjustment for reclassification and recalibration in the update framework for FY 2017.

The capital update framework also contains an adjustment for forecast error. The input price index forecast is based on historical trends and relationships ascertainable at the time the update factor is established for the upcoming year. In any given year, there may be unanticipated price fluctuations that may result in differences between the actual increase in prices and the forecast used in calculating the update factors. In setting a prospective payment rate under the framework, we make an adjustment for forecast error only if our estimate of the change in the capital input price index for any year is off by 0.25 percentage point or more. There is a 2-year lag between the forecast and the availability of data to develop a measurement of the forecast error. Historically, when a forecast error of the CIPI is greater than 0.25 percentage point in absolute terms, it is reflected in the update recommended under this framework. A forecast error of −0.3 percentage point was calculated for the FY 2015 update, for which there are historical data. That is, current historical data indicate that the forecasted FY 2015 CIPI (1.5 percent) used in calculating the FY 2015 update factor was 0.3 percentage points higher than actual realized price increases (1.2 percent). This over-prediction was primarily due to prices from municipal bond yields declining in 2015 whereas the forecast projected an increase. Therefore, we are proposing to make a −0.3 percentage point adjustment for forecast error in the update for FY 2017.

Under the capital IPPS update framework, we also make an adjustment for changes in intensity. Historically, we calculated this adjustment using the same methodology and data that were used in the past under the framework for operating IPPS. The intensity factor for the operating update framework reflected how hospital services are utilized to produce the final product, that is, the discharge. This component accounts for changes in the use of quality-enhancing services, for changes within DRG severity, and for expected modification of practice patterns to remove noncost-effective services. Our intensity measure is based on a 5-year average.

We calculate case-mix constant intensity as the change in total cost per discharge, adjusted for price level changes (the CPI for hospital and related services) and changes in real case-mix. Without reliable estimates of the proportions of the overall annual intensity increases that are due, respectively, to ineffective practice patterns and the combination of quality-enhancing new technologies and complexity within the DRG system, we assume that one-half of the annual increase is due to each of these factors. The capital update framework thus provides an add-on to the input price index rate of increase of one-half of the estimated annual increase in intensity, to allow for increases within DRG severity and the adoption of quality-enhancing technology.

In this proposed rule, we are continuing to use a Medicare-specific intensity measure that is based on a 5-year adjusted average of cost per discharge for FY 2017 (we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50436) for a full description of our Medicare-specific intensity measure). Specifically, for FY 2017, we are using an intensity measure that is based on an average of cost per discharge data from the 5-year period beginning with FY 2010 and extending through FY 2014. Based on these data, we estimated that case-mix constant intensity declined during FYs 2010 through 2014. In the past, when we found intensity to be declining, we believed a zero (rather than a negative) intensity adjustment was appropriate. Consistent with this approach, because we estimate that intensity declined during that 5-year period, we believe it is appropriate to continue to apply a zero intensity adjustment for FY 2017. Therefore, we are proposing to make a 0.0 percentage point adjustment for intensity in the update for FY 2017.

Above, we described the basis of the components used to develop the proposed 0.9 percent capital update factor under the capital update framework for FY 2017 as shown in the following table.

PROPOSED CMS FY 2017 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

Capital Input Price Index*	1.2
Intensity:	0.0
Case-Mix Adjustment Factors:	
Real Across DRG Change	0.5
Projected Case-Mix Change	0.5
Subtotal	1.2
Effect of FY 2015 Reclassification and Recalibration	0.0
Forecast Error Correction	−0.3
Total Update	0.9

*The capital input price index represents the FY 2010-based CIPI.

b. Comparison of CMS and MedPAC Update Recommendation

In its March 2016 Report to Congress, MedPAC did not make a specific update recommendation for capital IPPS payments for FY 2017. (We refer readers to MedPAC's Report to the Congress: Medicare Payment Policy, March 2016, Chapter 3, available on the Web site at: *http://www.medpac.gov.*)

2. Proposed Outlier Payment Adjustment Factor

Section 412.312(c) establishes a unified outlier payment methodology for inpatient operating and inpatient capital-related costs. A single set of thresholds is used to identify outlier cases for both inpatient operating and inpatient capital-related payments. Section 412.308(c)(2) provides that the standard Federal rate for inpatient capital-related costs be reduced by an adjustment factor equal to the estimated proportion of capital-related outlier payments to total inpatient capital-related PPS payments. The outlier thresholds are set so that operating outlier payments are projected to be 5.1 percent of total operating IPPS DRG payments.

For FY 2016, we estimated that outlier payments for capital would equal 6.35 percent of inpatient capital-related payments based on the capital Federal rate in FY 2016. Based on the proposed thresholds as set forth in section II.A. of this Addendum, we estimate that outlier payments for capital-related costs will equal 6.26 percent for inpatient capital-related payments based on the proposed capital Federal rate in FY 2017. Therefore, we are proposing to apply an outlier adjustment factor of 0.9374 in determining the capital Federal rate for FY 2017. Thus, we estimate that the percentage of capital outlier payments to total capital Federal rate payments for FY 2017 will be lower than the percentage for FY 2016.

The outlier reduction factors are not built permanently into the capital rates; that is, they are not applied cumulatively in determining the capital Federal rate. The proposed FY 2017 outlier adjustment of 0.9374 is a 0.10 percent change from the FY 2016 outlier adjustment of 0.9365. Therefore, the net change in the outlier adjustment to the proposed capital Federal rate for FY 2017 is 1.0010 (0.9374/0.9365). Thus, the proposed outlier adjustment will increase the FY 2017 capital Federal rate by 0.10 percent compared to the FY 2016 outlier adjustment.

3. Proposed Budget Neutrality Adjustment Factor for Changes in DRG Classifications and Weights and the GAF

Section 412.308(c)(4)(ii) requires that the capital Federal rate be adjusted so that aggregate payments for the fiscal year based on the capital Federal rate after any changes resulting from the annual DRG reclassification and recalibration and changes in the GAF are projected to equal aggregate payments that would have been made on the basis of the capital Federal rate without such changes. Because we are proposing to determine capital IPPS payments to hospitals located in Puerto Rico based on 100 percent of the capital Federal rate beginning in FY 2017, we have not calculated a separate GAF for Puerto Rico, and therefore, we are not applying a separate budget neutrality adjustment for the Puerto Rico GAF. Similarly, the budget neutrality factor for DRG reclassifications and recalibration nationally is applied in determining the capital IPPS Federal rate, and is applicable for all hospitals, including those hospitals located in Puerto Rico.

To determine the proposed national capital rate factors for FY 2017, we compared estimated aggregate capital Federal rate payments based on the FY 2016 MS–DRG classifications and relative weights and the FY 2016 GAF to estimated aggregate capital Federal rate payments based on the FY 2016 MS–DRG classifications and relative weights and the proposed FY 2017 GAFs. To achieve budget neutrality for the changes in the national GAFs, based on calculations using updated data, we are proposing to apply an incremental budget neutrality adjustment factor of 0.9997 for FY 2017 to the previous cumulative FY 2016 adjustment factor of 0.9860, yielding an adjustment factor of 0.9857 through FY 2017.

We then compared estimated aggregate capital Federal rate payments based on the FY 2016 MS–DRG relative weights and the proposed FY 2017 GAFs to estimated aggregate capital Federal rate payments based on the cumulative effects of the proposed FY 2017 MS–DRG classifications and relative weights and the proposed FY 2017 GAFs. The proposed incremental adjustment factor for DRG classifications and changes in relative weights is 0.9996. The proposed cumulative adjustment factor for MS–DRG classifications and proposed changes in relative weights and for proposed changes in the GAFs through FY 2017 is 0.9853. (We note that all the values are calculated with unrounded numbers.)

The GAF/DRG budget neutrality adjustment factors are built permanently into the capital rates; that is, they are applied cumulatively in determining the capital Federal rate. This follows the requirement under § 412.308(c)(4)(ii) that estimated aggregate payments each year be no more or less than they would have been in the absence of the annual DRG reclassification and recalibration and changes in the GAFs.

The methodology used to determine the recalibration and geographic adjustment factor (GAF/DRG) budget neutrality adjustment is similar to the methodology used in establishing budget neutrality adjustments under the IPPS for operating costs. One difference is that, under the operating IPPS, the budget neutrality adjustments for the effect of geographic reclassifications are determined separately from the effects of other changes in the hospital wage index and the MS–DRG relative weights. Under the capital IPPS, there is a single GAF/DRG budget neutrality adjustment factor for changes in the GAF (including geographic reclassification) and the MS–DRG relative weights. In addition, there is no adjustment for the effects that geographic reclassification has on the other payment parameters, such as the payments for DSH or IME.

The proposed cumulative adjustment factor of 0.9993 (the product of the proposed incremental national GAF budget neutrality adjustment factor of 0.9997 and the proposed incremental DRG budget neutrality adjustment factor of 0.9996) accounts for the MS–DRG reclassifications and recalibration and for changes in the GAFs. It also incorporates the effects on the GAFs of FY 2017 geographic reclassification decisions made by the MGCRB compared to FY 2016 decisions. However, it does not account for changes in payments due to changes in the DSH and IME adjustment factors.

As discussed in section V.C. of the preamble of this proposed rule, we are proposing to make an adjustment of (1/0.998) to the proposed national capital Federal rate to remove the 0.2 percent reduction (an adjustment factor of 0.998) to the national capital Federal rate to offset the estimated increase in capital IPPS expenditures associated with the 2-midnight policy. This is consistent with the proposed adjustment to the operating IPPS standardized amount and the hospital-specific payment rates. In addition, consistent with the approach proposed for the operating IPPS standardized amount and hospital-specific payment rates and for the reasons discussed in sections IV.O. and V.C. of the preamble of this proposed rule, we are proposing a one-time prospective adjustment of 1.006 in FY 2017 to the proposed national capital Federal rate to address the effect of the 0.2 percent reduction to the national capital Federal rates in effect for FY 2014, FY 2015, and FY 2016. We also are proposing to remove this one-time prospective adjustment through an adjustment of (1/1.006) to the national capital Federal rate in FY 2018, consistent with the approach proposed for the operating IPPS standardized amount and hospital-specific payment rates (as discussed in section IV.O. of the preamble of this proposed rule). We refer readers to sections IV.O. and V.C. of the preamble of this proposed rule for a complete discussion of these proposals.

4. Proposed Capital Federal Rate for FY 2017

For FY 2016, we established a capital Federal rate of $438.75 (as revised, in the FY 2016 IPPS/LTCH PPS correction notice CMS–1632–CN2 (80 FR 60060 and 60061)). We are proposing to establish an update of 0.9 percent in determining the FY 2017 capital Federal rate for all hospitals. As a result of this proposed update, the proposed budget neutrality factors discussed earlier, and the proposed adjustments to remove the 0.2 percent reductions (both the (1/0.998) adjustment to permanently remove the 0.2 percent reduction and the one-time 0.6 percent adjustment) resulting from the 2-midnight policy, we are proposing to establish a national capital Federal rate of $446.35 for FY 2017. The proposed national capital Federal rate for FY 2017 was calculated as follows:

- The proposed FY 2017 update factor is 1.009, that is, the proposed update is 0.9 percent.
- The proposed FY 2017 budget neutrality adjustment factor that is applied to the capital Federal rate for changes in the MS–DRG classifications and relative weights and changes in the GAFs is 0.9993.
- The proposed FY 2017 outlier adjustment factor is 0.9374.

- The proposed 2-midnight policy adjustment to permanently remove the 0.2 percent reduction is (1/0.998).
- The proposed 2-midnight one-time policy adjustment is 1.006.

(We note that, as discussed in section V.C. of the preamble of this proposed rule, we are not making an additional MS–DRG documentation and coding adjustment to the proposed capital IPPS Federal rate for FY 2017.)

Because the proposed FY 2017 capital Federal rate has already been adjusted for differences in case-mix, wages, cost-of-living, indirect medical education costs, and payments to hospitals serving a disproportionate share of low-income patients, we are not proposing to make additional adjustments in the capital Federal rate for these factors, other than the budget neutrality factor for changes in the MS–DRG classifications and relative weights and for changes in the GAFs.

We are providing the following chart that shows how each of the proposed factors and adjustments for FY 2017 affects the computation of the proposed FY 2017 national capital Federal rate in comparison to the FY 2016 national capital Federal rate. The proposed FY 2017 update factor has the effect of increasing the capital Federal rate by 0.9 percent compared to the FY 2016 capital Federal rate. The proposed GAF/DRG budget neutrality adjustment factor has the effect of decreasing the proposed capital Federal rate by 0.07 percent. The proposed FY 2017 outlier adjustment factor has the effect of increasing the proposed capital Federal rate by 0.10 percent compared to the FY 2016 capital Federal rate. The proposed permanent 2-midnight policy adjustment has the effect of increasing the proposed capital Federal rate by 0.2 percent and the proposed temporary 2-midnight policy adjustment has the effect of increasing the proposed capital Federal rate by 0.6 percent. The combined effect of all the proposed changes would increase the proposed national capital Federal rate by approximately 1.7 percent compared to the FY 2016 national capital Federal rate.

COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2016 CAPITAL FEDERAL RATE AND PROPOSED FY 2017 CAPITAL FEDERAL RATE

	FY 2016	Proposed FY 2017	Change	Percent change
Update Factor [1]	1.0130	1.009	1.009	0.9
GAF/DRG Adjustment Factor [1]	0.9976	0.9993	0.9993	−0.07
Outlier Adjustment Factor [2]	0.9365	0.9374	1.0010	0.10
Permanent 2-midnight Policy Adjustment Factor	N/A	1.002	1.002	0.2
One-Time 2-midnight Policy Adjustment Factor	N/A	1.006	1.006	0.6
Capital Federal Rate	$438.75	$446.35	1.0173	1.73

[1] The proposed update factor and the proposed GAF/DRG budget neutrality adjustment factors are built permanently into the capital Federal rates. Thus, for example, the incremental change from FY 2016 to FY 2017 resulting from the application of the proposed 0.9993 GAF/DRG budget neutrality adjustment factor for FY 2017 is a net change of 0.9993 (or −0.07 percent).

[2] The proposed outlier reduction factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the proposed FY 2017 outlier adjustment factor is 0.9374/0.9365, or 1.0010 (or 0.10 percent).

B. Calculation of the Proposed Inpatient Capital-Related Prospective Payments for FY 2017

For purposes of calculating payments for each discharge during FY 2017, the capital Federal rate is adjusted as follows: (Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME Adjustment Factor, if applicable). The result is the adjusted capital Federal rate.

Hospitals also may receive outlier payments for those cases that qualify under the thresholds established for each fiscal year. Section 412.312(c) provides for a single set of thresholds to identify outlier cases for both inpatient operating and inpatient capital-related payments. The proposed outlier thresholds for FY 2017 are in section II.A. of this Addendum. For FY 2017, a case would qualify as a cost outlier if the cost for the case plus the (operating) IME and DSH payments (including both the empirically justified Medicare DSH payment and the estimated uncompensated care payment, as discussed in section II.A.4.g.(1) of this Addendum) is greater than the prospective payment rate for the MS–DRG plus the proposed fixed-loss amount of $23,681.

Currently, as provided under § 412.304(c)(2), we pay a new hospital 85 percent of its reasonable costs during the first 2 years of operation unless it elects to receive payment based on 100 percent of the capital Federal rate. Effective with the third year of operation, we pay the hospital based on 100 percent of the capital Federal rate (that is, the same methodology used to pay all other hospitals subject to the capital PPS).

C. Capital Input Price Index

1. Background

Like the operating input price index, the capital input price index (CIPI) is a fixed-weight price index that measures the price changes associated with capital costs during a given year. The CIPI differs from the operating input price index in one important aspect—the CIPI reflects the vintage nature of capital, which is the acquisition and use of capital over time. Capital expenses in any given year are determined by the stock of capital in that year (that is, capital that remains on hand from all current and prior capital acquisitions). An index measuring capital price changes needs to reflect this vintage nature of capital. Therefore, the CIPI was developed to capture the vintage nature of capital by using a weighted-average of past capital purchase prices up to and including the current year.

We periodically update the base year for the operating and capital input price indexes to reflect the changing composition of inputs for operating and capital expenses. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50603 through 50607), we rebased and revised the CIPI to a FY 2010 base year to reflect the more current structure of capital costs in hospitals. For a complete discussion of this rebasing, we refer readers to the FY 2014 IPPS/LTCH PPS final rule.

2. Forecast of the CIPI for FY 2017

Based on the latest forecast by IHS Global Insight, Inc. (first quarter of 2016), we are forecasting the FY 2010-based CIPI to increase 1.2 percent in FY 2017. This reflects a projected 1.6 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 2.6 percent increase in other capital expense prices in FY 2017, partially offset by a projected 1.5 percent decline in vintage-weighted interest expense prices in FY 2017. The weighted average of these three factors produces the forecasted 1.2 percent increase for the FY 2010-based CIPI as a whole in FY 2017.

IV. Proposed Changes to Payment Rates for Excluded Hospitals: Proposed Rate-of-Increase Percentages for FY 2017

Payments for services furnished in children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) that are excluded from the IPPS are made on the basis of reasonable costs based on the hospital's own historical cost experience, subject to a rate-of-increase ceiling. A per discharge limit (the target amount as defined in § 413.40(a) of the regulations) is set for each hospital based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. (We note that, in accordance with § 403.752(a), RNHCIs are also subject to the rate-of-increase limits established under § 413.40 of the regulations.)

In this proposed rule, the FY 2017 rate-of-increase percentage for updating the target amounts for the 11 cancer hospitals, children's hospitals, the short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and RNHCIs is the estimated percentage increase in the IPPS operating market basket for FY 2017, in accordance with applicable regulations at § 413.40. Based on IHS Global Insight, Inc.'s 2016 first quarter forecast, we estimated that the FY 2010-based IPPS operating market basket update for FY 2017 would be 2.8 percent (that is, the estimate of the market basket rate-of-increase). However, we proposed that if more recent data become available for the final rule, we would use them to calculate the IPPS operating market basket update for FY 2017. Therefore, based on IHS Global Insight, Inc.'s 2016 first quarter forecast, with historical data through 2015 fourth quarter, we estimate that the FY 2010-based IPPS operating market basket update for FY 2017 is 2.8 percent (that is, the estimate of the market basket rate-of-increase). For children's hospitals, the 11 cancer hospitals, hospitals located outside the 50 States, the District of Columbia and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa), and RNHCIs, the proposed FY 2017 rate-of-increase percentage that would be applied to the FY 2016 target amounts in order to determine the proposed FY 2017 target amounts is 2.8 percent.

The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section VII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule for the proposed update changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2017. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

V. Proposed Changes to the Payment Rates for the LTCH PPS for FY 2017

A. Proposed LTCH PPS Standard Federal Payment Rate for FY 2017

1. Background

In section VII. of the preamble of this proposed rule, we discuss our proposed annual updates to the payment rates, factors, and specific policies under the LTCH PPS for FY 2017.

Under § 412.523(c)(3)(ii) of the regulations, for LTCH PPS rate years beginning RY 2004 through RY 2006, we updated the standard Federal rate annually by a factor to adjust for the most recent estimate of the increases in prices of an appropriate market basket of goods and services for LTCHs. We established this policy of annually updating the standard Federal rate because, at that time, we believed that was the most appropriate method for updating the LTCH PPS standard Federal rate for years after the initial implementation of the LTCH PPS in FY 2003. Therefore, under § 412.523(c)(3)(ii), for RYs 2004 through 2006, the annual update to the LTCH PPS standard Federal rate was equal to the previous rate year's Federal rate updated by the most recent estimate of increases in the appropriate market basket of goods and services included in covered inpatient LTCH services.

In determining the annual update to the standard Federal rate for RY 2007, based on our ongoing monitoring activity, we believed that, rather than solely using the most recent estimate of the LTCH PPS market basket update as the basis of the annual update factor, it was appropriate to adjust the standard Federal rate to account for the effect of documentation and coding in a prior period that was unrelated to patients' severity of illness (71 FR 27818). Accordingly, we established under § 412.523(c)(3)(iii) that the annual update to the standard Federal rate for RY 2007 was zero percent based on the most recent estimate of the LTCH PPS market basket at that time, offset by an adjustment to account for changes in case-mix in prior periods due to the effect of documentation and coding that were unrelated to patients' severity of illness. For RY 2008 through FY 2011, we also made an adjustment to account for the effect of documentation and coding that was unrelated to patients' severity of illness in establishing the annual update to the standard Federal rate as set forth in the regulations at §§ 412.523(c)(3)(iv) through (c)(3)(vii). For FYs 2012 through 2016, we updated the standard Federal rate by the most recent estimate of the LTCH PPS market basket at that time, including additional statutory adjustments required by section 1886(m)(3)(A) of the Act as set forth in the regulations at §§ 412.523(c)(3)(viii) through (c)(3)(ix).

Section 1886(m)(3)(A) of the Act, as added by section 3401(c) of the Affordable Care Act, specifies that, for rate year 2010 and each subsequent rate year, any annual update to the standard Federal rate shall be reduced:

- For rate year 2010 through 2019, by the other adjustment specified in section 1886(m)(3)(A)(ii) and (m)(4) of the Act; and
- For rate year 2012 and each subsequent year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (which we refer to as "the multifactor productivity (MFP) adjustment") as discussed in section VII.E.2. of the preamble of this proposed rule.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year. (As noted in section VII.E.2.a. of the preamble of this proposed rule, the annual update to the LTCH PPS occurs on October 1 and we have adopted the term "fiscal year" (FY) rather than "rate year" (RY) under the LTCH PPS beginning October 1, 2010. Therefore, for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we use the term "fiscal year" rather than "rate year" for 2011 and subsequent years.)

For FY 2016, consistent with our historical practice, we established an update to the LTCH PPS standard Federal payment rate based on the full estimated LTCH PPS market basket increase of 2.4 percent and the 0.7 percentage point reductions required by sections 1886(m)(3)(A)(i) and 1886(m)(3)(A)(ii) with 1886(m)(4)(E) of the Act. Accordingly, at § 412.523(c)(3)(xii) of the regulations, we established an annual update of 1.7 percent to the standard Federal payment rate for FY 2016 (80 FR 49636 through 49637). In addition, as discussed in that same final rule, the annual update for FY 2016 was further reduced by 2.0 percentage points for LTCHs that failed to submit quality reporting data in accordance with the requirements of the LTCH QRP under section 1886(m)(5) of the Act.

For FY 2017, in this proposed rule, based on the best available data, we are proposing an annual update to the LTCH PPS standard Federal payment rate of 1.45 percent, which is based on the full estimated increase in the LTCH PPS market basket of 2.7 percent, less the MFP adjustment of 0.5 percentage point consistent with section 1886(m)(3)(A)(i) of the Act, and less the 0.75 percentage point required by sections 1886(m)(3)(A)(ii) and (m)(4)(F) of the Act. (As discussed in section VII.E. of the preamble of this proposed rule, we are proposing to rebase and revise the 2009-based LTCH-specific market basket to reflect a 2013 base year.) For LTCHs that fail to submit the required quality reporting data for FY 2017 in accordance with the LTCH QRP, the annual update is further reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act (as discussed in greater detail in section VII.E.2.c. of the preamble of this proposed rule). Accordingly, we are proposing an annual update to the LTCH PPS standard Federal payment rate of −0.55 percent for LTCHs that fail to submit the required quality reporting data for FY 2017. This proposed −0.55 percent update was calculated based on the full estimated increase in the LTCH PPS market basket of 2.7 percent, less a MFP adjustment of 0.5 percentage point, less an additional adjustment of 0.75 percentage point required by the statute, and less 2.0 percentage points for failure to submit quality reporting data as required by section 1886(m)(5) of the Act.

2. Development of the Proposed FY 2017 LTCH PPS Standard Federal Payment Rate

We continue to believe that the annual update to the LTCH PPS standard Federal payment rate should be based on the most recent estimate of the increase in the LTCH PPS market basket, including any statutory adjustments. Consistent with our historical practice, for FY 2017, we are proposing to apply the annual update to the LTCH PPS standard Federal payment rate from the previous year. Furthermore, in determining the LTCH PPS standard Federal payment rate for FY 2017, we also are proposing to make certain regulatory adjustments, consistent with past practices. Specifically, in determining the proposed FY 2017 LTCH PPS standard Federal payment rate, we are proposing to apply a budget neutrality adjustment factor for the proposed changes related to the area wage adjustment (that is, changes to the wage data and labor-related share) in accordance with § 412.523(d)(4). We also are proposing to use more recent data to determine the update to the LTCH PPS standard Federal payment rate for FY 2017 in the final rule.

For FY 2016, we established an annual update to the LTCH PPS standard Federal payment rate of 1.7 percent based on the full estimated LTCH PPS market basket increase of 2.4 percent, less the MFP adjustment of 0.5 percentage point consistent with section 1886(m)(3)(A)(i) of the Act and less the 0.2 percentage point required by sections 1886(m)(3)(A)(ii) and (m)(4)(E) of the Act. Accordingly, at § 412.523(c)(3)(xii), we established an annual update to the LTCH PPS standard Federal payment rate for FY 2015 of 1.7 percent. That is, we applied an update factor of 1.017 to the FY 2015 Federal rate of $41,043.71 to determine the FY 2016 LTCH PPS standard Federal payment rate. We also applied an area wage level budget neutrality factor for FY 2016 of 1.000513 to the LTCH PPS standard Federal payment rate to ensure that any changes to the area wage level adjustment would not result in any change in estimated aggregate LTCH PPS payments. Consequently, we established a LTCH PPS standard Federal payment rate for FY 2016 of $41,762.85 (calculated as $41,043.71 × 1.017 × 1.000513) (80 FR 49797).

In this proposed rule, we are proposing an annual update to the LTCH PPS standard Federal payment rate of 1.45 percent, which was determined using the methodology previously described. Accordingly, under § 412.523(c)(3)(xiii), we are proposing to apply a factor of 1.0145 to the FY 2017 LTCH PPS standard Federal payment rate of $41,762.85 to determine the proposed FY 2017 LTCH PPS standard Federal payment rate. These factors are based on IGI's first quarter 2016 forecast, which are the best available data at this time. For LTCHs that fail to submit quality reporting data for FY 2017 under the LTCH QRP, under proposed § 412.523(c)(3)(xiii), applied in conjunction with the provisions of § 412.523(c)(4), we are proposing to reduce the annual update to the LTCH PPS standard Federal payment rate by an additional 2.0 percentage points, consistent with section 1886(m)(5) of the Act. In those cases, the LTCH PPS standard Federal payment rate is updated by -0.55 percent (that is, a proposed update factor of 0.9945) for FY 2017 for LTCHs that fail to submit the required quality reporting data for FY 2017 as required under the LTCH QRP. Consistent with § 412.523(d)(4), we also are proposing to apply an area wage level budget neutrality factor to the FY 2017 LTCH PPS standard Federal payment rate of 0.998723, which was determined using the methodology described below in section V.B.4. of this Addendum. We are proposing to apply this area wage level budget neutrality factor to the FY 2017 LTCH PPS standard Federal payment rate to ensure that any proposed changes to the area wage level adjustment (that is, the proposed annual update of the wage index values and labor-related share) will not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. Accordingly, we are proposing a LTCH PPS standard Federal payment rate of $42,314.31 (calculated as $41,762.85 × 1.0145 × 0.998723) for FY 2017. For LTCHs that fail to submit quality reporting data for FY 2017 in accordance with the requirements of the LTCHQRP under section 1886(m)(5) of the Act, we are proposing a LTCH PPS standard Federal payment rate of $41,480.12 (calculated as $41,762.85× 0.9945 × 0.998723) for FY 2017. We note, as discussed in section VII.B. of the preamble of this proposed rule, under our application of the site neutral payment rate required under section 1886(m)(6) of the Act, this LTCH PPS standard Federal payment rate will only be used to determine payments for LTCH PPS standard Federal payment rate cases (that is, those LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate).

B. Proposed Adjustment for Area Wage Levels Under the LTCH PPS for FY 2017

1. Background

Under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS standard Federal payment rate to account for differences in LTCH area wage levels under § 412.525(c). The labor-related share of the LTCH PPS standard Federal payment rate is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. The applicable LTCH PPS wage index is computed using wage data from inpatient acute care hospitals without regard to reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act.

When we implemented the LTCH PPS, we established a 5-year transition to the full area wage level adjustment. The area wage level adjustment was completely phased-in for cost reporting periods beginning in FY 2007. Therefore, for cost reporting periods beginning on or after October 1, 2006, the applicable LTCH area wage index values are the full LTCH PPS area wage index values calculated based on acute care hospital inpatient wage index data without taking into account geographic reclassification under section 1886(d)(8) and section 1886(d)(10) of the Act. For additional information on the phase-in of the area wage level adjustment under the LTCH PPS, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56015 through 56019) and the RY 2008 LTCH PPS final rule (72 FR 26891).

2. Proposed Geographic Classifications (Labor Market Areas) for the LTCH PPS Standard Federal Payment Rate

In adjusting for the differences in area wage levels under the LTCH PPS, the labor-related portion of an LTCH's Federal prospective payment is adjusted by using an appropriate area wage index based on the geographic classification (labor market area) in which the LTCH is located. Specifically, the application of the LTCH PPS area wage level adjustment under existing § 412.525(c) is made based on the location of the LTCH—either in an "urban area," or a "rural area," as defined in § 412.503. Under § 412.503, an "urban area" is defined as a Metropolitan Statistical Area (MSA) (which includes a Metropolitan division, where applicable), as defined by the Executive OMB and a "rural area" is defined as any area outside of an urban area. (Information on OMB's MSA delineations based on the 2010 standards can be found at: *http://www.whitehouse.gov/sites/default/files/omb/assets/fedreg_2010/06282010_metro_standards-Complete.pdf*).

The CBSA-based geographic classifications (labor market area definitions) currently used under the LTCH PPS, effective for discharges occurring on or after October 1, 2014, are based on the OMB labor market area delineations based on the 2010 Decennial Census data. The current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. We adopted these labor market area delineations because they are based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas. We also believe that these OMB delineations will ensure that the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level. We noted that this policy was consistent with the IPPS policy adopted in FY 2015 under § 412.64(b)(1)(ii)(D) of the regulations (79 FR 49951 through 49963). (For additional information on the CBSA-based labor market area (geographic classification) delineations currently used under the LTCH PPS and the history of the labor market area definitions used under the LTCH PPS, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50180 through 50185).)

In general, it is our historical practice to update the CBSA-based labor market area delineations annually based on the most recent updates issued by OMB. Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provides updates to and supersedes OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provides detailed information on the update to statistical areas since February 28, 2013. As discussed in section III.A.2. of the preamble of this proposed rule, the updates provided in OMB Bulletin No. 15–01 are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. A copy of this bulletin may be obtained on the Web site at: *https://www.whitehouse.gov/omb/bulletins_/*.

OMB Bulletin No. 15–01 made the following changes that are relevant to the LTCH PPS CBSA-based labor market area (geographic classification) delineations:

- Garfield County, OK, with principal city Enid, OK, which was a Micropolitan (geographically rural) area, now qualifies as an urban area under new CBSA 21420 entitled Enid, OK.
- The county of Bedford City, VA, a component of the Lynchburg, VA CBSA

31340, changed to town status and is added to Bedford County. Therefore, the county of Bedford City is now part of the county of Bedford, VA. The CBSA remains Lynchburg, VA, 31340.

- The name of Macon, GA, CBSA 31420, as well as a principal city of the Macon-Warner Robins, GA combined statistical area, is now Macon-Bibb County, GA. The CBSA code remains as 31420.

We believe that these revisions to the CBSA-based labor market area delineations will ensure that the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas and, therefore, we are proposing to adopt them under the LTCH PPS, effective October 1, 2016. Accordingly, the proposed FY 2017 LTCH PPS wage index values in Tables 12A and 12B listed in section VI. of the Addendum of this proposed rule (which are available via the Internet on the CMS Web site) reflect the revisions to the CBSA-based labor market area delineations described above. We note that, as discussed in section III.C.2. of the preamble of this proposed rule, the revisions to the CBSA-based delineations also are proposed for adoption under the IPPS, effective beginning October 1, 2016.

3. Proposed Labor-Related Share for the LTCH PPS Standard Federal Payment Rate

Under the payment adjustment for the differences in area wage levels under § 412.525(c), the labor-related share of an LTCH's standard Federal payment rate payment is adjusted by the applicable wage index for the labor market area in which the LTCH is located. The LTCH PPS labor-related share currently represents the sum of the labor-related portion of operating costs (Wages and Salaries; Employee Benefits; Professional Fees Labor-Related, Administrative and Business Support Services; and All-Other: Labor-Related Services) and a labor-related portion of capital costs using the applicable LTCH PPS market basket. Additional background information on the historical development of the labor-related share under the LTCH PPS can be found in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817 and 27829 through 27830) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766 through 51769 and 51808).

For FY 2013, we revised and rebased the market basket used under the LTCH PPS by adopting the newly created FY 2009-based LTCH-specific market basket. In addition, beginning in FY 2013, we determined the labor-related share annually as the sum of the relative importance of each labor-related cost category of the 2009-based LTCH-specific market basket for the respective fiscal year based on the best available data. (For more details, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53477 through 53479).) As noted previously, we are proposing to rebase and revise the 2009-based LTCH-specific market basket to reflect a 2013 base year. In conjunction with that proposal, as discussed in section VII.D.4.e. of the preamble of this proposed rule, we are proposing that the LTCH PPS labor-related share for FY 2017 would be the sum of the FY 2017 relative importance of each labor-related cost category in the proposed 2013-based LTCH market basket using the most recent available data. Specifically, we are proposing that the labor related share for FY 2017 would include the sum of the labor-related portion of operating costs from the proposed 2013-based LTCH market basket (that is, the sum of the FY 2017 relative importance share of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related Services) and a portion of the Capital-Related cost weight from the proposed 2013-based LTCH PPS market basket. Based on IGI's first quarter 2016 forecast of the proposed 2013-based LTCH market basket, we are proposing a labor-related share under the LTCH PPS for FY 2017 of 66.6 percent. This proposed labor-related share is determined using the same methodology as employed in calculating all previous LTCH PPS labor-related shares. Consistent with our historical practice, we are proposing to use more recent data to determine the final FY 2017 labor-related share in the final rule.

Table VII–9 in section VII.D.4.e. of the preamble of this proposed rule shows the proposed FY 2017 relative importance labor-related share using the proposed 2013-based LTCH market basket and the FY 2016 relative importance labor-related share using the 2009-based LTCH-specific market basket. The proposed labor-related share for FY 2017 is the sum of the proposed FY 2017 relative importance of each labor-related cost category, and would reflect the different rates of price change for these cost categories between the base year (2013) and FY 2017. The sum of the proposed relative importance for FY 2017 for operating costs (Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related Services) is 62.3 percent. We are proposing that the portion of capital-related costs that is influenced by the local labor market is estimated to be 46 percent (the same percentage applied to the 2009-based LTCH-specific market basket). Because the relative importance for capital-related costs under our proposals would be 9.4 percent of the proposed 2013-based LTCH market basket in FY 2017, we are proposing to take 46 percent of 9.4 percent to determine the proposed labor-related share of capital-related costs for FY 2017 (0.46 x 9.4). The result is 4.3 percent, which we are proposing to add to 62.3 percent for the operating cost amount to determine the total proposed labor-related share for FY 2017. Therefore, the proposed labor-related share under the LTCH PPS for FY 2017 is 66.6 percent. We note that the proposed FY 2017 labor-related share using the proposed 2013-based LTCH market basket is 4.6 percentage points higher than the FY 2016 labor-related share using the 2009-based LTCH-specific market basket. This is primarily due to, as discussed in greater detail in section VII.D.4.e. of the preamble of this proposed rule, the change in the quantity of labor, particularly for professional services, outpacing the change in quantity of products (which are not included in the labor-related share) between 2009 and 2013, which more than offsets the faster relative growth in prices for products.

4. Proposed Wage Index for FY 2017 for the LTCH PPS Standard Federal Payment Rate

Historically, we have established LTCH PPS area wage index values calculated from acute care IPPS hospital wage data without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act (67 FR 56019). The area wage level adjustment established under the LTCH PPS is based on an LTCH's actual location without regard to the "urban" or "rural" designation of any related or affiliated provider.

In the FY 2016 LTCH PPS final rule (80 FR 49798through 49799), we calculated the FY 2016 LTCH PPS area wage index values using the same data used for the FY 2016 acute care hospital IPPS (that is, data from cost reporting periods beginning during FY 2012), without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act, as these were the most recent complete data available at that time. In that same final rule, we indicated that we computed the FY 2016 LTCH PPS area wage index values, consistent with the urban and rural geographic classifications (labor market areas) that were in place at that time and consistent with the pre-reclassified IPPS wage index policy (that is, our historical policy of not taking into account IPPS geographic reclassifications in determining payments under the LTCH PPS). As with the IPPS wage index, wage data for multicampus hospitals with campuses located in different labor market areas (CBSAs) are apportioned to each CBSA where the campus (or campuses) are located. We also continued to use our existing policy for determining area wage index values for areas where there are no IPPS wage data.

Consistent with our historical methodology, to determine the applicable area wage index values for the FY 2017 LTCH PPS standard Federal payment rate, under the broad authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we are proposing to use wage data collected from cost reports submitted by IPPS hospitals for cost reporting periods beginning during FY 2013, without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act, because these data are the most recent complete data available. We also note that these are the same data we are using to compute the proposed FY 2017 acute care hospital inpatient wage index, as discussed in section III. of the preamble of this proposed rule. We are computing the proposed FY 2017 LTCH PPS standard Federal payment rate area wage index values consistent with the "urban" and "rural" geographic classifications (that is, labor market area delineations, including the proposed updates, as previously discussed in section V.B.2. of this Addendum) and our historical policy of not taking into account

IPPS geographic reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act in determining payments under the LTCH PPS. We also are proposing to continue to apportion wage data for multicampus hospitals with campuses located in different labor market areas to each CBSA where the campus or campuses are located, consistent with the IPPS policy. Lastly, consistent with our existing methodology for determining the LTCH PPS wage index values, for FY 2017 we are proposing to continue to use our existing policy for determining area wage index values for areas where there are no IPPS wage data.

Under our existing methodology, the LTCH PPS wage index value for urban CBSAs with no IPPS wage data would be determined by using an average of all of the urban areas within the State and the LTCH PPS wage index value for rural areas with no IPPS wage data would be determined by using the unweighted average of the wage indices from all of the CBSAs that are contiguous to the rural counties of the State.

Based on the FY 2013 IPPS wage data that we are using to determine the proposed FY 2017 LTCH PPS standard Federal payment rate area wage index values in this proposed rule, there are no IPPS wage data for the urban area of Hinesville, GA (CBSA 25980). Consistent with the methodology discussed above, we calculated the proposed FY 2017 wage index value for CBSA 25980 as the average of the wage index values for all of the other urban areas within the state of Georgia (that is, CBSAs 10500, 12020, 12060, 12260, 15260, 16860, 17980, 19140, 23580, 31420, 40660, 42340, 46660 and 47580), as shown in Table 12A, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet on the CMS Web site). We note that, as IPPS wage data are dynamic, it is possible that urban areas without IPPS wage data will vary in the future.

Based on the FY 2013 IPPS wage data that we are using to determine the proposed FY 2017 LTCH PPS standard Federal payment rate area wage index values in this proposed rule, there are no rural areas without IPPS hospital wage data. Therefore, it is not necessary to use our established methodology to calculate a proposed LTCH PPS standard Federal payment rate wage index value for rural areas with no IPPS wage data for FY 2017. We note that, as IPPS wage data are dynamic, it is possible that the number of rural areas without IPPS wage data will vary in the future. The proposed FY 2017 LTCH PPS standard Federal payment rate wage index values that would be applicable for LTCH PPS standard Federal payment rate discharges occurring on or after October 1, 2016, through September 30, 2017, are presented in Table 12A (for urban areas) and Table 12B (for rural areas), which are listed in section VI. of the Addendum of this proposed rule and available via the Internet on the CMS Web site.

5. Proposed Budget Neutrality Adjustment for Changes to the LTCH PPS Standard Federal Payment Rate Area Wage Level Adjustment

Historically, the LTCH PPS wage index and labor-related share are updated annually based on the latest available data. Under § 412.525(c)(2), any changes to the area wage index values or labor-related share are to be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are unaffected; that is, will be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment. Under this policy, we determine an area wage-level adjustment budget neutrality factor that will be applied to the standard Federal payment rate to ensure that any changes to the area wage level adjustments are budget neutral such that any changes to the area wage index values or labor-related share would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Accordingly, under § 412.523(d)(4), we apply an area wage level adjustment budget neutrality factor in determining the standard Federal payment rate, and we also established a methodology for calculating an area wage level adjustment budget neutrality factor. (For additional information on the establishment of our budget neutrality policy for changes to the area wage level adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771 through 51773 and 51809).)

In this proposed rule, for FY 2017 LTCH PPS standard Federal payment rate cases, in accordance with § 412.523(d)(4), we are proposing to apply an area wage level adjustment budget neutrality factor to adjust the LTCH PPS standard Federal payment rate to account for the estimated effect of the proposed adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments using a methodology that is consistent with the methodology we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51773). Specifically, we are proposing to determine an area wage level adjustment budget neutrality factor that would be applied to the LTCH PPS standard Federal payment rate under § 412.523(d)(4) for FY 2017 using the following methodology:

Step 1—We simulated estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2016 wage index values and the FY 2016 labor-related share of 62.0 percent (as established in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49798 and 49799).

Step 2—We simulated estimated aggregate LTCH PPS standard Federal payment rate payments using the proposed FY 2017 wage index values (as shown in Tables 12A and 12B listed in the Addendum to this proposed rule and available via the Internet on the CMS Web site) and the proposed FY 2017 labor-related share of 66.6 percent (based on the latest available data as previously discussed previously in this Addendum).

Step 3—We calculated the ratio of these estimated total LTCH PPS standard Federal payment rate payments by dividing the estimated total LTCH PPS standard Federal payment rate payments using the FY 2016 area wage level adjustments (calculated in Step 1) by the estimated total LTCH PPS standard Federal payment rate payments using the proposed FY 2017 area wage level adjustments (calculated in Step 2) to determine the proposed area wage level adjustment budget neutrality factor for FY 2017 LTCH PPS standard Federal payment rate payments.

Step 4—We then applied the proposed FY 2017 area wage level adjustment budget neutrality factor from Step 3 to determine the proposed FY 2017 LTCH PPS standard Federal payment rate after the application of the proposed FY 2017 annual update (discussed previously in section V.A.2. of this Addendum).

We note that, with the exception of cases subject to the transitional blend payment rate provisions in the first 2 years, under the dual rate LTCH PPS payment structure, only LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid based on the LTCH PPS standard Federal payment rate. Because the area wage level adjustment under § 412.525(c) is an adjustment to the LTCH PPS standard Federal payment rate, we only used data from claims that would have qualified for payment at the LTCH PPS standard Federal payment rate if such rate were in effect at the time of discharge to calculate the FY 2017 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor described above.

For this proposed rule, using the steps in the methodology previously described, we determined a proposed FY 2017 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor of 0.998723. Accordingly, in section V.A.2. of the Addendum to this propose rule, to determine the proposed FY 2017 LTCH PPS standard Federal payment rate, we are applying a proposed area wage level adjustment budget neutrality factor of 0.998723, in accordance with § 412.523(d)(4). The proposed FY 2017 LTCH PPS standard Federal payment rate shown in Table 1E of the Addendum to this proposed rule reflects this adjustment factor.

C. Proposed Cost-of-Living Adjustment (COLA) for LTCHs Located in Alaska and Hawaii

Under § 412.525(b), a cost-of-living adjustment (COLA) is provided for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States. Specifically, we apply a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal payment rate by the applicable COLA factors established annually by CMS. Higher labor-related costs for LTCHs located in Alaska and Hawaii are taken into account in the adjustment for area wage levels previously described.

Under our current methodology, we update the COLA factors for Alaska and Hawaii every 4 years (at the same time as the update to the labor-related share of the IPPS market basket) (77 FR 53712 through 53713). This methodology is based on a comparison of the growth in the Consumer Price Indexes (CPIs) for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). It also includes a 25-percent cap on the CPI-updated COLA factors. (For additional details on our current methodology for updating the COLA factors for Alaska and Hawaii, we refer readers to section VII.D.3. of the preamble of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53481 through 53482).)

We continue to believe that determining updated COLA factors using this methodology would appropriately adjust the nonlabor-related portion of the LTCH PPS standard Federal payment rate for LTCHs located in Alaska and Hawaii. Under our current policy, we update the COLA factors using the methodology described above every 4 years; the first year began in FY 2014 (77 FR 53482). Therefore, in this proposed rule for FY 2017, under the broad authority conferred upon the Secretary by section 123 of the BBRA, as amended by section 307(b) of the BIPA, to determine appropriate payment adjustments under the LTCH PPS, we are proposing to continue to use the COLA factors based on the 2009 OPM COLA factors updated through 2012 by the comparison of the growth in the CPIs for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as established in the FY 2014 IPPS/LTCH PPS final rule. (We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50998) for a discussion of the FY 2014 COLA factors.) Consistent with our historical practice, we are proposing to establish that the COLA factors shown in the following table will be used to adjust the nonlabor-related portion of the LTCH PPS standard Federal payment rate for LTCHs located in Alaska and Hawaii under § 412.525(b).

PROPOSED COST-OF-LIVING ADJUSTMENT FACTORS FOR ALASKA AND HAWAII HOSPITALS UNDER THE LTCH PPS FOR FY 2017

Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.23
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.23
City of Juneau and 80-kilometer (50-mile) radius by road	1.23
All other areas of Alaska	1.25
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.19
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

D. Proposed Adjustment for LTCH PPS High-Cost Outlier (HCO) Cases

1. HCO Background

From the beginning of the LTCH PPS, we have included an adjustment to account for cases in which there are extraordinarily high costs relative to the costs of most discharges. Under this policy, additional payments are made based on the degree to which the estimated cost of a case (which is calculated by multiplying the Medicare allowable covered charge by the hospital's overall hospital CCR) exceeds a fixed-loss amount. This policy results in greater payment accuracy under the LTCH PPS and the Medicare program, and the LTCH sharing the financial risk for the treatment of extraordinarily high-cost cases.

We retained the basic tenets of our HCO policy in FY 2016 when we implemented the dual rate LTCH PPS payment structure under section 1206 of Public Law 113–67. LTCH discharges that meet the criteria for exclusion from site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid at the LTCH PPS standard Federal payment rate, which includes, as applicable, HCO payments under § 412.523(e). LTCH discharges that do not meet the criteria for exclusion are paid at the site neutral payment rate, which includes, as applicable, HCO payments under § 412.522(c)(2)(i). In the same rule, we established separate fixed-loss amounts and targets for the two different LTCH PPS payment rates. Under this bifurcated policy, the historic 8 percent HCO target was retained for LTCH PPS standard Federal payment rate cases, with the fixed-loss amount calculated using only data from LTCH cases which would have been paid at the LTCH PPS standard Federal payment rate if that rate had been in effect at the time of those discharges. For site neutral payment rate cases, we adopted the operating IPPS HCO target (currently 5.1 percent) and set the fixed-loss amount for site neutral payment rate cases at the value of the IPPS fixed-loss amount. Under the HCO policy for both payment rates, an LTCH receives 80 percent of the difference between the estimated cost of the case and the applicable HCO threshold, which is the sum of the LTCH PPS payment for the case and the applicable fixed-loss amount for such case. In order to maintain budget neutrality, consistent with the budget neutrality requirement for HCO payments to LTCH PPS standard Federal rate payment cases, we also adopted a budget neutrality requirement for HCO payments to site neutral payment rate cases by applying a budget neutrality factor to the LTCH PPS payment for those site neutral payment rate cases. (We refer readers to § 412.522(c)(2)(i) of the regulation for further details). We note during the 2-year transitional period, the site neutral payment rate HCO budget neutrality factor does not apply to the LTCH PPS standard Federal payment rate portion of the blended rate at § 412.522(c)(3) payable to site neutral payment rate cases. (For additional details on the HCO policy adopted for site neutral payment rate cases under the dual rate LTCH PPS payment structure, including the budget neutrality adjustment for HCO payments to site neutral payment rate cases, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49617 through 49623).)

2. Determining LTCH CCRs under the LTCH PPS

a. Background

As noted above, CCRs are used to determine payments for HCO adjustments for both payment rates under the LTCH PPS, and are also used to determine payments for SSO cases under § 412.529 as well as payments for site neutral payment rate cases. (We note that the provisions of § 412.529 are only applicable to LTCH PPS standard Federal payment rate cases.) Therefore, this discussion is relevant to all HCO, SSO, and site neutral payment rate calculations.

As noted earlier, in determining HCO, SSO, and the site neutral payment rate (regardless of whether the case is also an HCO) payments, we generally calculate the estimated cost of the case by multiplying the LTCH's overall CCR by the Medicare allowable charges for the case. An overall CCR is used because the LTCH PPS uses a single prospective payment per discharge that covers both inpatient operating and capital-related costs. The LTCH's overall CCR is generally computed based on the sum of LTCH operating and capital costs (as described in Section 150.24, Chapter 3, of the Medicare Claims Processing Manual (Pub. 100–4)) as compared to total Medicare charges (that is, the sum of its operating and capital inpatient routine and ancillary charges), with those values determined from either the most recently settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period. However, in certain instances, we use an alternative CCR, such as the statewide average CCR, a CCR that is specified by CMS, or one that is requested by the hospital. (We refer readers to § 412.525(a)(4)(iv) of the regulations for further details regarding HCO adjustments for either LTCH PPS payment rate, § 412.529(f)(4) for SSO adjustments, and § 412.522(c)(1)(ii) for the site neutral payment rate, respectively.)

The LTCH's calculated CCR is then compared to the LTCH total CCR ceiling. Under our established policy, an LTCH with a calculated CCR in excess of the applicable maximum CCR threshold (that is, the LTCH total CCR ceiling, which is calculated as 3 standard deviations from the national geometric average CCR) is generally assigned the applicable statewide CCR. This policy is premised on a belief that calculated CCRs above the LTCH total CCR ceiling are most likely due to faulty data reporting or entry, and CCRs based on erroneous data should not be used to identify and make payments for outlier cases.

b. LTCH Total CCR Ceiling

In this proposed rule, using our established methodology for determining the LTCH total CCR ceiling based on IPPS total CCR data from the December 2015 update of the Provider Specific File (PSF), we are proposing a LTCH total CCR ceiling of 1.302 under the LTCH PPS for FY 2017 in accordance with § 412.525(a)(4)(iv)(C)(*2*) for HCO cases under either payment rate, § 412.529(f)(4)(iii)(B) for SSOs, and § 412.522(c)(1)(ii) for the site neutral payment rate. Consistent with our historical practice, we also are proposing to use more recent data to determine the LTCH total CCR ceiling for the FY 2017 final rule. (For additional information on our methodology for determining the LTCH total CCR ceiling, we refer readers to the FY 2007 IPPS final rule (71 FR 48118 through 48119).)

c. LTCH Statewide Average CCRs

Our general methodology for determining the statewide average CCRs used under the LTCH PPS is similar to our established methodology for determining the LTCH total CCR ceiling because it is based on "total" IPPS CCR data. (For additional information on our methodology for determining statewide average CCRs under the LTCH PPS, we refer readers to the FY 2007 IPPS final rule (71 FR 48119 through 48120).) Under the LTCH PPS HCO policy for cases paid under either payment rate at § 412.525(a)(4)(iv)(C), the SSO policy at § 412.529(f)(4)(iii), and the site neutral payment rate at § 412.522(c)(1)(ii), the MAC may use a statewide average CCR, which is established annually by CMS, if it is unable to determine an accurate CCR for an LTCH in one of the following circumstances: (1) New LTCHs that have not yet submitted their first Medicare cost report, a new LTCH is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18); (2) LTCHs whose calculated CCR is in excess of the LTCH total CCR ceiling; and (3) other LTCHs for whom data with which to calculate a CCR are not available (for example, missing or faulty data). (Other sources of data that the MAC may consider in determining an LTCH's CCR include data from a different cost reporting period for the LTCH, data from the cost reporting period preceding the period in which the hospital began to be paid as an LTCH (that is, the period of at least 6 months that it was paid as a short-term, acute care hospital), or data from other comparable LTCHs, such as LTCHs in the same chain or in the same region.)

Consistent with our historical practice of using the best available data, in this proposed rule, using our established methodology for determining the LTCH statewide average CCRs, based on the most recent complete IPPS "total CCR" data from the December 2015 update of the PSF, we are proposing LTCH PPS statewide average total CCRs for urban and rural hospitals that would be effective for discharges occurring on or after October 1, 2016 through September 30, 2017, in Table 8C listed in section VI. of the Addendum to this proposed rule (and available via the Internet on the CMS Web site). Consistent with our historical practice, we are proposing to use more recent data to determine the LTCH PPS statewide average total CCRs for FY 2017 in the final rule.

Under the current LTCH PPS labor market areas, all areas in Delaware, the District of Columbia, New Jersey, and Rhode Island are classified as urban. Therefore, there are no rural statewide average total CCRs listed for those jurisdictions in Table 8C. This policy is consistent with the policy that we established when we revised our methodology for determining the applicable LTCH statewide average CCRs in the FY 2007 IPPS final rule (71 FR 48119 through 48121) and is the same as the policy applied under the IPPS. In addition, although Connecticut and North Dakota have areas that are designated as rural, in our calculation of the LTCH statewide average CCRs, there was no data available from short-term, acute care IPPS hospitals to compute a rural statewide average CCR or there were no short-term, acute care IPPS hospitals or LTCHs located in those areas as of December 2015. Therefore, consistent with our existing methodology, we are proposing to use the national average total CCR for rural IPPS hospitals for rural Connecticut and North Dakota in Table 8C listed in section VI. of the Addendum to this proposed rule (and available via the Internet on the CMS Web site). Furthermore, consistent with our existing methodology, in determining the urban and rural statewide average total CCRs for Maryland LTCHs paid under the LTCH PPS, we are proposing to continue to use, as a proxy, the national average total CCR for urban IPPS hospitals and the national average total CCR for rural IPPS hospitals, respectively. We use this proxy because we believe that the CCR data in the PSF for Maryland hospitals may not be entirely accurate (as discussed in greater detail in the FY 2007 IPPS final rule (71 FR 48120)).

d. Reconciliation of HCO and SSO Payments

Under the HCO policy for cases paid under either payment rate at § 412.525(a)(4)(iv)(D) and the SSO policy at § 412.529(f)(4)(iv), the payments for HCO and SSO cases are subject to reconciliation. Specifically, any such payments are reconciled at settlement based on the CCR that is calculated based on the cost report coinciding with the discharge. (We note the existing reconciliation process for HCO payments is also applicable to LTCH PPS payments for site neutral payment rate cases (80 FR 49610).) For additional information on the reconciliation policy, we refer readers to Sections 150.26 through 150.28 of the Medicare Claims Processing Manual (Pub. 100–4) as added by Change Request 7192 (Transmittal 2111; December 3, 2010) and the RY 2009 LTCH PPS final rule (73 FR 26820 through 26821).

e. Proposed Technical Change to the Definition of "Outlier Payment"

The existing regulations at § 412.503 includes a definition of "outlier payment," which was adopted when the LTCH PPS was implemented (67 FR 56049). This definition does not account for the dual rate LTCH PPS payment structure that began in FY 2016. Therefore, in this proposed rule, to account for our HCO policy for LTCH cases paid under either payment rate, we are proposing to revise the definition of "outlier payment" at § 412.503 to mean an additional payment beyond the LTCH PPS standard Federal payment rate or the site neutral payment rate (including, when applicable, the transitional blended rate), as applicable, for cases with unusually high costs.

3. Proposed High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

a. Establishment of the Proposed Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2017

When we implemented the LTCH PPS, we established a fixed-loss amount so that total estimated outlier payments are projected to equal 8 percent of total estimated payments under the LTCH PPS (67 FR 56022 through 56026). When we implemented the dual rate LTCH PPS payment structure beginning in FY 2016, we established that, in general, that the historical LTCH PPS HCO policy will continue to apply to LTCH PPS standard Federal payment rate cases. That is, the fixed-loss amount and target for LTCH PPS standard Federal payment rate cases is determined using the LTCH PPS HCO policy adopted when the LTCH PPS was first implemented, but we limited the data used under that policy to LTCH cases that would have been LTCH PPS standard Federal payment rate cases if the statutory changes had been in effect at the time of those discharges.

To determine the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases, we estimate outlier payments and total LTCH PPS payments for each LTCH PPS standard Federal payment rate case (or for each case that would have been a LTCH PPS standard Federal payment rate case if the statutory changes had been in effect at the time of the discharge) using claims data from the MedPAR files. The applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases results in estimated total outlier payments being projected to be equal to 8 percent of projected total LTCH PPS payments for LTCH PPS standard Federal payment rate cases. We use MedPAR claims data and CCRs based on data from the most recent PSF (or from the applicable statewide average CCR if an LTCH's CCR data are faulty or unavailable) to establish an applicable fixed-loss threshold amount for LTCH PPS standard Federal payment rate cases.

For FY 2017, we are not proposing to make any modifications to the current LTCH PPS HCO payment methodology for LTCH PPS standard Federal payment rate cases. Therefore, for FY 2017, we are proposing to determine an applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases using data from LTCH PPS standard Federal payment rate cases (or cases that would have been LTCH PPS standard Federal payment rate cases had the dual rate LTCH PPS payment structure been in effect at the time of those discharges). The proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases would continue to be determined so that estimated HCO payments would be projected to equal 8 percent of estimated total LTCH PPS standard Federal payment rate cases. Furthermore, in accordance with § 412.523(d)(1), a budget neutrality factor would continue to be applied to LTCH PPS standard Federal payment rate cases to offset that 8 percent so that HCO payments for LTCH PPS standard Federal payment rate cases will be budget neutral. Below we present our calculation of the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2017, which is consistent with the methodology used to establish the FY 2016 LTCH PPS fixed-loss amount.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49803 through 49804), we presented our policies regarding the methodology and data we used to establish a fixed-loss amount of $16,432 for FY 2016 for LTCH PPS standard Federal payment rate cases, which was calculated based on the data and the rates and policies presented in that final rule in order to maintain estimated HCO payments at the projected 8 percent of total estimated LTCH PPS payments. Consistent with our historical practice of using the best data available, in determining the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2017, we used the most recent available LTCH claims data and CCR data, that is, LTCH claims data from the December 2015 update of the FY 2015 MedPAR file and CCRs from the December 2015 update of the PSF, as these data were the most recent complete LTCH data available at that time.

For FY 2017, we are proposing to continue to use our current methodology to calculate an applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2017 using the best available data that would maintain estimated HCO payments at the projected 8 percent of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases (based on the rates and policies for these cases presented in this proposed rule). Specifically, based on the most recent complete LTCH data available (that is, LTCH claims data from the December 2015 update of the FY 2015 MedPAR file and CCRs from the December 2015 update of the PSF), we determined a proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2017 that will result in estimated outlier payments projected to be equal to 8 percent of estimated FY 2017 payments for such cases. Under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of the BIPA, we are proposing a fixed-loss amount of $22,728 for LTCH PPS standard Federal payment rate cases for FY 2017. Under our proposal, we would continue to make an additional HCO payment for the cost of an LTCH PPS standard Federal payment rate case that exceeds the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the adjusted LTCH PPS standard Federal payment rate payment and the fixed-loss amount for LTCH PPS standard Federal payment rate cases of $22,728).

We note that the proposed fixed-loss amount of $22,728 for FY 2017 for LTCH PPS standard Federal payment rate cases is notably higher than the FY 2016 fixed-loss amount for LTCH PPS standard Federal payment rate cases of $16,423. The FY 2016 fixed-loss amount for LTCH PPS standard Federal payment rate cases was determined using LTCH claims data from the March 2015 update of the FY 2014 MedPAR file and CCRs from the March 2015 update of the PSF. Based on that data, the estimated outlier payments were projected to be equal to 8 percent of estimated FY 2016 payments for such cases (80 FR 49803). Using the more recent LTCH claims data (that is, FY 2015 LTCH discharges from the December 2015 update of the MedPAR file and CCRs from the December 2015 update of the PSF), we currently estimate that the FY 2016 fixed-loss amount of $16,423 results in estimated HCO payments for LTCH PPS standard Federal payment rate cases of approximately 9.1 percent of total estimated FY 2016 LTCH PPS payments to those cases, which exceeds the 8 percent target. While many factors contribute to this increase, we found that the rate-of-change in the Medicare allowable charges on the claims data in the MedPAR is a significant contributing factor. In the payment modeling used to estimate LTCH PPS payments for the FY 2016 IPPS/LTCH PPS final rule, for SSO and HCO cases paid as LTCH PPS standard Federal payment rate cases, we applied an inflation factor of 4.6 percent (determined by the Office of the Actuary) to update the 2014 costs of each case to 2016 (80 FR 49833). Upon examining the FY 2014 LTCH discharge data and the FY 2015 discharge data, we found that Medicare allowable charges for LTCH PPS standard Federal payment rate cases (had the dual rate LTCH PPS payment structure been in effect at the time of the discharges) increased approximately 7 percent. This higher inflation factor results in higher estimated costs for outlier cases and, therefore, more estimated outlier payments.

Fluctuations in the fixed-loss amount occurred in the first few years after the implementation of the LTCH PPS, due, in part, to the changes in LTCH behavior (such as Medicare beneficiary treatment patterns) in response to the new payment system and the lack of data and information available to predict how those changes would affect the estimate costs of LTCH cases. As we gained more experience with the effects and implementation of the LTCH PPS, the annual changes on the fixed-loss amount generally stabilized relative to the fluctuations that occurred in the early years of the LTCH PPS. At this time, we are not proposing any changes to our method for the inflation factor applied to update the costs of each case (that is, an inflation factor based on the most recent estimate of the proposed 2013-based LTCH market basket as determined by the Office of the Actuary) in determining the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2017. We continue to believe that it is appropriate to continue to use our historical approach until we gain experience with the effects and implementation of the dual rate LTCH PPS payment structure that began with discharges occurring in cost reporting periods beginning on or after October 1, 2015, and the types of cases paid at the LTCH PPS standard Federal payment rate under this dual rate payment structure. We may revisit this issue in the future if data demonstrate such a change is warranted, and would propose any changes in the future through the notice-and-comment rulemaking process. However, we are inviting public comments on potential improvements to the determination of the fixed-loss amount for LTCH PPS standard Federal payment rate cases, including the most appropriate method of determining an inflation factor for projecting the costs of each case when determining the fixed-loss threshold.

For the reasons discussed above, we believe it is necessary and appropriate to propose an increase to the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2017 to maintain that, for LTCH PPS standard Federal payment rate cases, estimated HCO payments would equal 8 percent of estimated total LTCH PPS payments for those cases as required under § 412.525(a). (For further information on the existing 8 percent HCO "target" requirement, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56022 through 56024).) Maintaining the fixed-loss amount at the current level would result in HCO payments that are substantially more than the current regulatory 8 percent target that we are applying to total payments for LTCH PPS standard Federal payment rate cases because a lower fixed-loss amount would result in more cases qualifying as outlier cases, as well as higher outlier payments for qualifying HCO cases because the maximum loss that an LTCH must incur before receiving an HCO payment (that is, the fixed-loss amount) would be smaller.

b. Application of the High-Cost Outlier Policy to SSO Cases

Under our implementation of the dual rate LTCH PPS payment structure required by statute, LTCH PPS standard Federal payment rate cases (that is, LTCH discharges that meet the criteria for exclusion from the site neutral payment rate) will continue to be paid based on the LTCH PPS standard Federal payment rate, and will include all of the existing payment adjustments under § 412.525(d), such as the adjustments for SSO cases under § 412.529. Under some rare circumstances, an LTCH discharge can qualify as an SSO case (as defined in the regulations at § 412.529 in conjunction with § 412.503) and also as an HCO case, as discussed in the August 30, 2002 final rule (67 FR 56026). In this scenario, a patient could be hospitalized for less than five-sixths of the geometric average length of stay for the specific MS–LTC–DRG, and yet incur extraordinarily high treatment costs. If the estimated costs exceeded the HCO threshold (that is, the SSO payment plus the applicable fixed-loss amount), the discharge is eligible for payment as an HCO. Therefore, for an SSO case in FY 2017, we are proposing the HCO payment would be 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the proposed fixed-loss amount of $22,728 and the amount paid under the SSO policy as specified in § 412.529).

4. Proposed High-Cost Outlier Payments for Site Neutral Payment Rate Cases

Under § 412.525(a), site neutral payment rate cases receive an additional HCO payment for costs that exceed the HCO threshold that is equal to 80 percent of the difference between the estimated cost of the case and the applicable HCO threshold (80

FR 49618 through 49629). In the FY 2016 IPPS/LTCH PPS final rule, in examining the appropriate fixed-loss amount for site neutral payment rate cases issue, we considered how LTCH discharges based on historical claims data would have been classified under the dual rate LTCH PPS payment structure and the CMS' Office of the Actuary (OACT) projections regarding how LTCHs would likely respond to our proposed implementation of policies resulting from the statutory payment changes. For FY 2016, at that time our actuaries projected that the proportion of cases that would qualify as LTCH PPS standard Federal payment rate cases versus site neutral payment rate cases under the statutory provisions would remain consistent with what is reflected in the historical LTCH PPS claims data. Although our actuaries did not project an immediate change in the proportions found in the historical data, they did project cost and resource changes to account for the lower payment rates. Our actuaries also projected that the costs and resource use for cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and would likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what is found based on the historical data. In light of these projections and expectations, we discussed that we believed that the use of a single fixed-loss amount and HCO target for all LTCH PPS cases would be problematic. In addition, we discussed that we did not believe that it would be appropriate for comparable LTCH PPS site neutral payment rate cases to receive dramatically different HCO payments from those cases that would be paid under the IPPS (80 FR 49618 through 49619). For those reasons, in the FY 2016 IPPS/LTCH PPS final rule (FR 80 49619), we stated that we believe that the most appropriate fixed-loss amount for site neutral payment rate cases for a given fiscal year, beginning with FY 2016, would be the IPPS fixed-loss amount for that fiscal year. Accordingly, we established that for FY 2016, a fixed-loss amount for site neutral payment rate cases of $22,544, which was the same as the FY 2016 IPPS fixed-loss amount. (We note that the FY 2016 fixed-loss amount under the IPPS was updated, applicable for discharges on or after January 1, 2016, as a conforming change to the implementation of section 601 of the Consolidated Appropriations Act, 2016, which modified the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016 (Change Request 9523, Transmittal 3449, dated February 4, 2016).) Consistent with this change, the FY 2016 fixed-loss amount for site neutral payment rate cases under the LTCH PPS was updated, applicable for discharges on or after January 1, 2016, to $22,538, which is the same as the updated IPPS outlier fixed-loss cost threshold for FY 2016. (We refer readers to Change Request 9527, Transmittal 3445, dated January 29, 2016, which also updated the IPPS comparable amount calculation, applicable to discharges occurring on or after January 1, 2016, consistent with the conforming changes made as a result of the new IPPS payment requirement.)

For this proposed rule, in developing a proposed fixed-loss amount for site neutral payment rate cases for FY 2017, we considered the same factors we did developing a fixed-loss amount for such cases for FY 2016. For FY 2017, our actuaries currently project that the proportion of cases that would qualify as LTCH PPS standard Federal payment rate cases versus site neutral payment rate cases under the dual rate LTCH PPS payment structure provisions would remain consistent with what is reflected in the historical LTCH PPS claims data. Based on FY 2014 LTCH claims data, LTCH claims data, we found that approximately 55 percent of LTCH cases would have been paid the LTCH PPS standard Federal payment rate and approximately 45 percent of LTCH cases would have been paid the site neutral payment rate if those rates had been in effect at that time.) At this time, our actuaries continue to project no immediate change in these proportions. However, they do continue to project that the costs and resource use for cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and would likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what is found based on the historical data. As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49619), this actuarial assumption is based on our expectation that site neutral payment rate cases would generally be paid based on an IPPS comparable per diem amount under the statutory LTCH PPS payment changes that began in FY 2016, which, in the majority of cases, is much lower than the payment that would have been paid if these statutory changes were not enacted. For these reasons, we continue to believe that the most appropriate fixed-loss amount for site neutral payment rate cases for FY 2017 is the IPPS fixed-loss amount for FY 2017.

Therefore, for FY 2017, we are proposing that the applicable HCO threshold for site neutral payment rate cases is the sum of the site neutral payment rate for the case and the IPPS fixed-loss amount. That is, we are proposing a fixed-loss amount for site neutral payment rate cases of $23,681, which is the same proposed FY 2017 IPPS fixed-loss amount discussed in section II.A.4.g.(1). of the Addendum to this proposed rule. We continue to believe that this policy will reduce differences between HCO payments for similar cases under the IPPS and site neutral payment rate cases under the LTCH PPS and promote fairness between the two systems. Accordingly, under this proposal, for FY 2017, we would calculate a HCO payment for site neutral payment rate cases with costs that exceed the HCO threshold amount, which is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of site neutral payment rate payment and the proposed fixed-loss amount for site neutral payment rate cases of $23,681). (We note that any site neutral payment rate case that is paid 100 percent of the estimated cost of the case (because that amount is lower than the IPPS comparable per diem amount) will not be eligible to receive a HCO payment because, by definition, the estimated costs of such cases would never exceed the IPPS comparable per diem amount by any threshold.)

In establishing a HCO policy for site neutral payment rate cases, we established a budget neutrality requirement at § 412.522(c)(2)(i). We established this requirement because we believe that the HCO policy for site neutral payment rate cases should be budget neutral, just as the HCO policy for LTCH PPS standard Federal payment rate cases are budget neutral, meaning that estimated site neutral payment rate HCO payments should not result in any change in estimated aggregate LTCH PPS payments. Under § 412.522(c)(2)(i), we adjust all payments for site neutral payment rate cases by a budget neutrality factor so that the estimated HCO payments payable for site neutral payment rate cases do not result in any increase in aggregate LTCH PPS payments. Specifically, under § 412.522(c)(2)(i), we apply a budget neutrality factor to the site neutral payment rate portion of the transitional blended rate payment (that is applicable to site neutral payment rate cases during the 2-year transition period provided by the statute) that is established based on an estimated basis. (We refer readers to 80 FR 49621 through 49622 and 49805.)

Under the approach adopted for applying the budget neutrality adjustment to the site neutral payment rate portion of the transitional blended rate payment in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49805), we explained that there is no need to perform any calculation of the site neutral payment rate case HCO payment budget neutrality adjustment under our finalized policy. This is because, as discussed previously, based on our actuarial assumptions we project that our proposal to use the IPPS fixed-loss threshold for the site neutral payment rate cases would result in HCO payments for those cases that are similar in proportion as is seen in IPPS cases assigned to the same MS–DRG; that is, 5.1 percent. In other words, we estimated that HCO payments for site neutral payment rate cases would be 5.1 percent of the site neutral payment rate payments. Under the statutory transition period, payments to site neutral payment rate cases in FY 2017 will be paid under the blended transitional rate. As such, estimated HCO payments for site neutral payment rate cases in the FY 2017 proposal would be projected to be 5.1 percent of the portion of the blended rate payment that is based on the estimated site neutral payment rate payment amount (and would not include the LTCH PPS standard Federal payment rate payment amount as specified in § 412.522(c)(2)(i)). To ensure that estimated HCO payments payable to site neutral payment rate cases in FY 2017 would not result any increase in estimated aggregate FY 2017 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce the site neutral payment rate portion of the blended rate payment by 5.1 percent to account for the estimated additional HCO payments payable to those cases in FY 2017. In order to achieve this, for FY 2017, we are proposing to continue to apply a budget neutrality factor of 0.949 (that is, the decimal equivalent of a 5.1 percent reduction, determined as 1.0–5.1/100 = 0.949) to the site neutral payment rate portion of the blended rate payment (80 FR 49805). As stated previously, this adjustment is necessary so that the estimated HCO payments payable for site neutral payment rate cases do not result in any increase in aggregate LTCH PPS payments.

E. Proposed Update to the IPPS Comparable/Equivalent Amounts to Reflect the Statutory Changes to the IPPS DSH Payment Adjustment Methodology

In the FY 2014 IPPS/LTCH PPS final rule, we established a policy for reflecting the changes to the Medicare IPPS DSH payment adjustment methodology provided for by section 3133 of the Affordable Care Act in the calculation of the "IPPS comparable amount" under the SSO policy at § 412.529 and the "IPPS equivalent amount" under the 25-percent threshold payment adjustment policy at § 412.534 and § 412.536. Historically, the determination of both the "IPPS comparable amount" and the "IPPS equivalent amount" includes an amount for inpatient operating costs "for the costs of serving a disproportionate share of low-income patients." Under the statutory changes to the Medicare DSH payment adjustment methodology that began in FY 2014, in general, eligible IPPS hospitals receive an empirically justified Medicare DSH payment equal to 25 percent of the amount they otherwise would have received under the statutory formula for Medicare DSH payments prior to the amendments made by the Affordable Care Act. The remaining amount, equal to an estimate of 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals under the age of 65 who are uninsured, is made available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The additional uncompensated care payments are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all IPPS hospitals that receive Medicare DSH payments.

To reflect the statutory changes to the Medicare DSH payment adjustment methodology in the calculation of the "IPPS comparable amount" and the "IPPS equivalent amount" under the LTCH PPS, we stated that we will include a reduced Medicare DSH payment amount that reflects the projected percentage of the payment amount calculated based on the statutory Medicare DSH payment formula prior to the amendments made by the Affordable Care Act that will be paid to eligible IPPS hospitals as empirically justified Medicare DSH payments and uncompensated care payments in that year (that is, a percentage of the operating DSH payment amount that has historically been reflected in the LTCH PPS payments that is based on IPPS rates). We also stated that the projected percentage will be updated annually, consistent with the annual determination of the amount of uncompensated care payments that will be made to eligible IPPS hospitals. We believe that this approach results in appropriate payments under the LTCH PPS and is consistent with our intention that the "IPPS comparable amount" and the "IPPS equivalent amount" under the LTCH PPS closely resemble what an IPPS payment would have been for the same episode of care, while recognizing that some features of the IPPS cannot be translated directly into the LTCH PPS (79 FR 50766 through 50767).

For FY 2017, as discussed in greater detail in section IV.D.3.d.(2) of the preamble of this proposed rule, based on the most recent data available, our estimate of 75 percent of the amount that would otherwise have been paid as Medicare DSH payments (under the methodology outlined in section 1886(r)(2) of the Act) is adjusted to 56.74 percent of that amount to reflect the change in the percentage of individuals who are uninsured. The resulting amount is then used to determine the amount of uncompensated care payments that will be made to eligible IPPS hospitals in FY 2017. In other words, Medicare DSH payments prior to the amendments made by the Affordable Care Act would be adjusted to 42.56 percent (the product of 75 percent and 56.74 percent) and the resulting amount will be used to calculate the uncompensated care payments to eligible hospitals. As a result, for FY 2017, we project that the reduction in the amount of Medicare DSH payments pursuant to section 1886(r)(1) of the Act, along with the payments for uncompensated care under section 1886(r)(2) of the Act, would result in overall Medicare DSH payments of 67.56 percent of the amount of Medicare DSH payments that would otherwise have been made in the absence of amendments made by the Affordable Care Act (that is, 25 percent + 56.74 percent = 67.56 percent).

In this proposed rule, for FY 2017, we are proposing that the calculation of the "IPPS comparable amount" under § 412.529 and the "IPPS equivalent amount" under new § 412.538 would include an applicable operating Medicare DSH payment amount that is equal to 67.5677 percent of the operating Medicare DSH payment amount that would have been paid based on the statutory Medicare DSH payment formula but for the amendments made by the Affordable Care Act. Furthermore, consistent with our historical practice, we are proposing to use more recent data, if available, to determine this factor in the final rule.

F. Computing the Proposed Adjusted LTCH PPS Federal Prospective Payments for FY 2017

Section 412.525 sets forth the adjustments to the LTCH PPS standard Federal payment rate. Under the dual rate LTCH PPS payment structure, only LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate. Under § 412.525(c), the LTCH PPS standard Federal payment rate is adjusted to account for differences in area wages by multiplying the labor-related share of the LTCH PPS standard Federal payment for a case by the applicable LTCH PPS wage index (the proposed FY 2017 values are shown in Tables 12A through 12B listed in section VI. of the Addendum of this proposed rule and are available via the Internet on the CMS Web site). The LTCH PPS standard Federal payment is also adjusted to account for the higher costs of LTCHs located in Alaska and Hawaii by the applicable COLA factors (the proposed FY 2017 factors are shown in the chart in section V.D. of this Addendum) in accordance with § 412.525(b). In this proposed rule, we are proposing an LTCH PPS standard Federal payment rate for FY 2017 of $42,314.31, as discussed in section V.A.2. of the Addendum to this proposed rule. We illustrate the methodology to adjust the proposed LTCH PPS standard Federal payment rate for FY 2017 in the following example:

Example: During FY 2017, a Medicare discharge that meets the criteria to be excluded from the site neutral payment rate, that is an LTCH PPS standard Federal payment rate case, is from an LTCH that is located in Chicago, Illinois (CBSA 16974). The FY 2017 LTCH PPS proposed wage index value for CBSA 16974 is 1.0486 (obtained from Table 12A listed in section VI. of the Addendum of this proposed rule and available via the Internet on the CMS Web site). The Medicare patient case is classified into MS–LTC–DRG 189 (Pulmonary Edema & Respiratory Failure), which has a proposed relative weight for FY 2017 of 0.9107 (obtained from Table 11 listed in section VI. of the Addendum of this proposed rule and available via the Internet on the CMS Web site). The LTCH submitted quality reporting data for FY 2017 in accordance with the LTCHQRP under section 1886(m)(5) of the Act.

To calculate the LTCH's total proposed adjusted Federal prospective payment for this Medicare patient case in FY 2017, we computed the wage-adjusted Federal prospective payment amount by multiplying the unadjusted proposed FY 2017 LTCH PPS standard Federal payment rate ($42,314.31) by the proposed labor-related share (66.6 percent) and the wage index value (1.0486). This wage-adjusted amount was then added to the proposed nonlabor-related portion of the unadjusted LTCH PPS standard Federal payment rate (33.4 percent; adjusted for cost of living, if applicable) to determine the adjusted proposed LTCH PPS standard Federal payment rate, which is then multiplied by the proposed MS–LTC–DRG relative weight (0.9107) to calculate the total proposed adjusted LTCH PPS standard Federal prospective payment for FY 2017 ($39,782.95). The table below illustrates the components of the calculations in this example.

Proposed LTCH PPS Standard Federal Prospective Payment Rate	$42,314.31
Proposed Labor-Related Share	× 0.666
Proposed Labor-Related Portion of the LTCH PPS Standard Federal Payment Rate	= $28,181.33
Proposed Wage Index (CBSA 16974)	× 1.0486
Proposed Wage-Adjusted Labor Share of LTCH PPS Standard Federal Payment Rate	= $29,550.94
Proposed Nonlabor-Related Portion of the LTCH PPS Standard Federal Payment Rate ($42,314.31 × 0.334)	+ $14,132.98
Proposed Adjusted LTCH PPS Standard Federal Payment Amount	= $43,683.92
Proposed MS–LTC–DRG 189 Relative Weight	× 0.9107
Total Proposed Adjusted LTCH PPS Standard Federal Prospective Payment	= $39,782.95

VI. Tables Referenced in This Proposed Rule and Available Only Through the Internet on the CMS Web Site

This section lists the tables referred to throughout the preamble of this proposed rule and in this Addendum. In the past, a majority of these tables were published in the **Federal Register** as part of the annual proposed and final rules. However, similar to FYs 2012 through 2016, for the FY 2017 rulemaking cycle, the IPPS and LTCH tables will not be published in the **Federal Register** in the annual IPPS/LTCH PPS proposed and final rules and will be available only through the Internet. Specifically, all IPPS tables listed below, with the exception of IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E will be available only through the Internet. IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E are displayed at the end of this section and will continue to be published in the **Federal Register** as part of the annual proposed and final rules.

As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49807), we streamlined and consolidated the wage index tables for FY 2016 and subsequent fiscal years.

As discussed in sections II.F.14., II.F.15.b., II.F.16., II.F.17.a., and II.F.19.a.1., a.3., and c.1. of the preamble of this proposed rule, we developed the following ICD–10–CM and ICD–10–PCS code tables for FY 2017: Table 6A—New Diagnosis Codes; Table 6B—New Procedure Codes; Table 6C—Invalid Diagnosis Codes; Table 6G.1—Proposed Secondary Diagnosis Order Additions to the CC Exclusion List; Table 6G.2—Proposed Principal Diagnosis Order Additions to the CC Exclusion List; Table 6H.1—Proposed Secondary Diagnosis Order Deletions to the CC Exclusion List; Table 6H.2—Proposed Principal Diagnosis Order Deletions to the CC Exclusion List; Table 6I—Proposed Complete MCC List; Table 6I.1—Proposed Additions to MCC List; Table 6I.2—Proposed Deletions to MCC List; Table 6J—Proposed Complete CC List; Table 6J.1—Proposed Additions to CC List; Table 6J.2—Proposed Deletions to CC List; Table 6L—Proposed Principal Diagnosis Is Its Own MCC List; Table 6M—Proposed Principal Diagnosis Is Its Own CC List; Table 6M.1—Proposed Additions to the Principal Diagnosis Is Its Own CC List; and Table 6P—ICD–10–CM and ICD–10–PCS Codes for Proposed MCE and MS–DRG Changes. Table 6P contains multiple tables, 6P.1a through 6P.4k, that include the ICD–10–CM and ICD–10–PCS code lists and translations relating to specific MCE and MS–DRG proposed changes. In addition, under the HAC Reduction Program established by section 3008 of the Affordable Care Act, a hospital's total payment may be reduced by 1 percent if it is in the lowest HAC performance quartile. However, as discussed in section IV.F. of the preamble of this proposed rule, we are not providing the hospital-level data as a table associated with this proposed rule. The hospital-level data for the FY 2017 HAC Reduction Program will be made publicly available once it has undergone the review and corrections process.

Finally, a hospital's Factor 3 is the proportion of the uncompensated care amount that a DSH eligible hospital will receive under section 3133 of the Affordable Care Act. Factor 3 is the hospital's estimated number of Medicaid days and Medicare SSI days (or for a Puerto Rico hospital, a proxy for its Medicare SSI days) relative to the estimate of all DSH hospitals' Medicaid days and Medicare SSI days (or for Puerto Rico hospitals that are estimated to be eligible for DSH payments, a proxy for their Medicare SSI days). Table 18 associated with this proposed rule contains the FY 2017 Medicare DSH uncompensated care payment Factor 3 for all hospitals and identifies whether or not a hospital is projected to receive DSH and, therefore, eligible to receive the additional payment for uncompensated care for FY 2017.

Readers who experience any problems accessing any of the tables that are posted on the CMS Web sites identified below should contact Michael Treitel at (410) 786–4552.

The following IPPS tables for this FY 2017 proposed rule are available only through the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* Click on the link on the left side of the screen titled, "FY 2017 IPPS Proposed Rule Home Page" or "Acute Inpatient—Files for Download".

Table 2.—Proposed Case-Mix Index and Wage Index Table by CCN—FY 2017
Table 3.—Proposed Wage Index Table by CBSA—FY 2017
Table 5.—Proposed List of Proposed Medicare Severity Diagnosis-Related Groups (MS DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2017
Table 6A.—New Diagnosis Codes for FY 2017
Table 6B.—New Procedure Codes for FY 2017
Table 6C.—Invalid Diagnosis Codes for FY 2017
Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2017
Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2017
Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2017
Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2017
Table 6I.—Proposed Complete Major Complication and Comorbidity (MCC) List—FY 2017
Table 6I.1.—Proposed Additions to the MCC List—FY 2017
Table 6I.2.—Proposed Deletions to the MCC List—FY 2017
Table 6J.—Proposed Complete Complication and Comorbidity (CC) List—FY 2017
Table 6J.1.—Proposed Additions to the CC List—FY 2017
Table 6J.2.—Proposed Deletions to the CC List—FY 2017
Table 6L.—Proposed Principal Diagnosis Is Its Own MCC List—FY 2017
Table 6M.—Proposed Principal Diagnosis Is Its Own CC List—FY 2017
Table 6M.1.—Proposed Additions to the Principal Diagnosis Is Its Own CC List—FY 2017
Table 6P.—ICD–10–CM and ICD–10–PCS Codes for Proposed MCE and MS–DRG Changes—FY 2017
Table 7A.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2015 MedPAR Update—December 2015 GROUPER V33.0 MS–DRGs
Table 7B.—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2015 MedPAR Update—December 2015 GROUPER V34.0 MS–DRGs
Table 8A.—Proposed FY 2017 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)
Table 8B.—Proposed FY 2017 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals
Table 10.—Proposed New Technology Add-On Payment Thresholds for Applications for FY 2018
Table 14.—List of Hospitals with Fewer Than 1,600 Medicare Discharges Based on the December 2015 Update of the FY 2015 MedPAR File and Potentially Eligible Hospitals for the Proposed FY 2017 Low Volume Hospital Payment Adjustment (eligibility for the low-volume hospital payment adjustment is also dependent upon meeting the mileage criteria specified at 42 CFR 412.101(b)(2)(ii).)
Table 15.—Proposed FY 2017 Proxy Readmissions Adjustment Factors
Table 16.—Proposed Proxy Hospital Inpatient Value-Based Purchasing (VBP) Adjustment Factors for FY 2017
Table 18.—Proposed FY 2017 Medicare DSH Uncompensated Care Payment Factor 3

The following LTCH PPS tables for this FY 2017 proposed rule are available only through the Internet on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1655–P:

Table 8C.—Proposed FY 2017 Statewide Average Total Cost-to-Charge Ratios (CCRs) for LTCHs (Urban and Rural)
Table 11.—Proposed MS–LTC–DRGs, Relative Weights, Geometric Average Length of Stay, Short-Stay Outlier (SSO) Threshold, and "IPPS Comparable" Threshold for LTCH PPS Discharges Occurring from October 1, 2016 through September 30, 2017
Table 12A.—Proposed LTCH PPS Wage Index for Urban Areas for Discharges Occurring from October 1, 2016 through September 30, 2017
Table 12B.—Proposed LTCH PPS Wage Index for Rural Areas for Discharges Occurring from October 1, 2016 through September 30, 2017
Table 13A.—Proposed Composition of Low Volume Quintiles for MS–LTC–DRGs—FY 2017
Table 13B.—Proposed No Volume MS LTC–DRG Crosswalk for FY 2017

TABLE 1A—PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (69.6 PERCENT LABOR SHARE/30.4 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)—FY 2017

Hospital submitted quality data and is a meaningful EHR user (update = 1.55 percent)		Hospital submitted quality data and is NOT a meaningful EHR user (update = −0.55 percent)		Hospital did NOT submit quality data and is a meaningful EHR user (update = 0.850 percent)		Hospital did NOT submit quality data and is NOT a meaningful EHR user (update = −1.25 percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,836.20	$1,675.59	$3,756.87	$1,640.94	$3,809.76	$1,664.04	$3,730.43	$1,629.39

TABLE 1B—PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN 1)—FY 2017

Hospital submitted quality data and is a meaningful EHR user (update = 1.55 percent)		Hospital submitted quality data and is NOT a meaningful EHR user (update = −0.55 percent)		Hospital did NOT submit quality data and is a meaningful EHR user (update = 0.850 percent)		Hospital did NOT submit quality data and is NOT a meaningful EHR user (update = −1.25 percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,417.31	$2,094.48	$3,346.64	$2,051.17	$3,393.76	$2,080.04	$3,323.09	$2,036.73

TABLE 1C—PROPOSED ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR HOSPITALS IN PUERTO RICO, LABOR/NONLABOR (NATIONAL: 62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE BECAUSE WAGE INDEX IS LESS THAN OR EQUAL TO 1)—FY 2017

Standardized amount	Rates if wage index is greater than 1		Rates if wage index is less than or equal to 1	
	Labor	Nonlabor	Labor	Nonlabor
National[1]	Not Applicable	Not Applicable	$3,417.31	$2,094.48

[1] For FY 2017, there are no CBSAs in Puerto Rico with a national wage index greater than 1.

TABLE 1D—PROPOSED CAPITAL STANDARD FEDERAL PAYMENT RATE—FY 2017

	Rate
National	$446.35

TABLE 1E—PROPOSED LTCH PPS STANDARD FEDERAL PAYMENT RATE—FY 2017

	Full update (1.45 percent)	Reduced update* (−0.55 percent)
Standard Federal Rate	$42,314.31	$41,480.12

* For LTCHs that fail to submit quality reporting data for FY 2017 in accordance with the LTCH Quality Reporting Program (LTCH QRP), the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

Appendix A: Economic Analyses

I. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year).

We have determined that this proposed rule is a major rule as defined in 5 U.S.C. 804(2). We estimate that the proposed changes for FY 2017 acute care hospital operating and capital payments would redistribute amounts in excess of $100 million to acute care hospitals. The applicable percentage increase to the IPPS rates required by the statute, in conjunction with other proposed payment changes in this proposed rule, would result in an estimated $693 million increase in FY 2017 proposed operating payments (or 0.7 percent change) and an estimated $164 million increase in FY 2017 proposed capital payments (or 2.0 percent change). These proposed changes are relative to payments made in FY 2016. The impact analysis of the proposed capital payments can be found in section I.I. of this Appendix. In addition, as described in section I.J. of this Appendix, LTCHs are expected to experience a decrease in payments by $355 million in FY 2017 relative to FY 2016.

Our operating impact estimate includes the proposed −1.5 percent documentation and coding adjustment applied to the IPPS standardized amount, as discussed in section II.D. of the preamble of this proposed rule, which represents part of the recoupment required under section 631 of the ATRA. In addition, our operating payment impact estimate includes the proposed 1.55 percent hospital update to the standardized amount (which includes the estimated 2.8 percent market basket update less 0.5 percentage point for the proposed multifactor productivity adjustment and less 0.75 percentage point required under the Affordable Care Act). Our operating payment impact estimate also includes a proposed adjustment of (1/0.998) to permanently remove the −0.2 percent reduction and a proposed 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 as a result of the 2-midnight policy (we refer readers to section IV.O. of the preamble of this proposed rule for an explanation of these proposed adjustments). The estimates of IPPS operating payments to acute care hospitals do not reflect any changes in hospital admissions or real case-mix intensity, which will also affect overall proposed payment changes.

The analysis in this Appendix, in conjunction with the remainder of this document, demonstrates that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. This proposed rule would affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant. Finally, in accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget has reviewed this proposed rule.

B. Statement of Need

This proposed rule is necessary in order to make payment and policy changes under the Medicare IPPS for Medicare acute care hospital inpatient services for operating and capital-related costs as well as for certain hospitals and hospital units excluded from the IPPS. This proposed rule also is necessary to make payment and policy changes for Medicare hospitals under the LTCH PPS.

C. Objectives of the IPPS

The primary objective of the IPPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the changes in this proposed rule would further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these proposed changes will ensure that the outcomes of the prospective payment systems are reasonable and equitable while avoiding or minimizing unintended adverse consequences.

D. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our proposed policy changes, as well as statutory changes effective for FY 2017, on various hospital groups. We estimate the effects of individual proposed policy changes by estimating payments per case while holding all other payment policies constant. We use the best data available, but, generally, we do not attempt to make adjustments for future changes in such variables as admissions, lengths of stay, or case-mix.

E. Hospitals Included in and Excluded From the IPPS

The prospective payment systems for hospital inpatient operating and capital-related costs of acute care hospitals encompass most general short-term, acute care hospitals that participate in the Medicare program. There were 31 Indian Health Service hospitals in our database, which we excluded from the analysis due to the special characteristics of the prospective payment methodology for these hospitals. Among other short-term, acute care hospitals, hospitals in Maryland are paid in accordance with the Maryland All-Payer Model, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, 5 short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling.

As of March 2016, there were 3,330 IPPS acute care hospitals included in our analysis. This represents approximately 55 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There also are approximately 1,374 CAHs. These small, limited service hospitals are paid on the basis of reasonable costs rather than under the IPPS. IPPS-excluded hospitals and units, which are paid under separate payment systems, include IPFs, IRFs, LTCHs, RNHCIs, children's hospitals, 11 cancer hospitals, and 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. Changes in the prospective payment systems for IPFs and IRFs are made through separate rulemaking. Payment impacts of changes to the prospective payment systems for these IPPS-excluded hospitals and units are not included in this proposed rule. The impact of the proposed update and proposed policy changes to the LTCH PPS for FY 2017 is discussed in section I.J. of this Appendix.

F. Effects on Hospitals and Hospital Units Excluded From the IPPS

As of March 2016, there were 98 children's hospitals, 11 cancer hospitals, 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa, and 18 RNHCIs being paid on a reasonable cost basis subject to the rate-of-increase ceiling under § 413.40. (In accordance with § 403.752(a) of the regulation, RNHCIs are paid under § 413.40.) Among the remaining providers, 262 rehabilitation hospitals and 869 rehabilitation units, and approximately 430 LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and 495 psychiatric hospitals and 1,122 psychiatric units are paid the Federal per diem amount under the IPF PPS. As stated previously, IRFs and IPFs are not affected by the rate updates discussed in this proposed rule. The impacts of the changes on LTCHs are discussed in section I.J. of this Appendix.

For children's hospitals, the 11 cancer hospitals, the 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and RNHCIs, the update of the rate-of-increase limit (or target amount) is the estimated FY 2017 percentage increase in the IPPS operating market basket, consistent with section 1886(b)(3)(B)(ii) of the Act, and §§ 403.752(a) and 413.40 of the regulations. As discussed in section IV. of the preamble of the FY 2014 IPPS/LTCH PPS final rule, we rebased the IPPS operating market basket to a FY 2010 base year. Therefore, we are using the percentage increase in the FY 2010-based IPPS operating market basket to update the target amounts for FY 2017 and subsequent fiscal years for children's hospitals, the 11 cancer hospitals, the 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and RNHCIs that are paid based on reasonable costs subject to the rate-of-increase limits. Consistent with current law, based on IHS Global Insight, Inc.'s first quarter 2016 forecast of the FY 2010-based IPPS market basket increase, we are estimating the FY 2017 update to be 2.8 percent (that is, the current estimate of the market basket rate-of-increase). However, the Affordable Care Act requires an adjustment for multifactor productivity (currently estimated to be 0.5 percentage point for FY 2017) and a 0.75 percentage point reduction to the market basket update, resulting in a 1.55 percent applicable percentage increase for IPPS hospitals that submit quality data and are meaningful EHR users, as discussed in section IV.B. of the preamble of this proposed rule. Children's hospitals, the 11 cancer hospitals, the 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and RNHCIs that continue to be paid based on reasonable costs subject to rate-of-increase limits under § 413.40 of the regulations are not subject to the reductions in the applicable percentage increase required under the Affordable Care Act. Therefore, for those hospitals paid under § 413.40 of the regulations, the update is the percentage increase in the FY 2010-based IPPS operating market basket for FY 2017, estimated at 2.8 percent, without the reductions described previously under the Affordable Care Act.

The impact of the update in the rate-of-increase limit on those excluded hospitals depends on the cumulative cost increases experienced by each excluded hospital since its applicable base period. For excluded hospitals that have maintained their cost increases at a level below the rate-of-increase limits since their base period, the major effect is on the level of incentive payments these excluded hospitals receive. Conversely, for excluded hospitals with cost increases above the cumulative update in their rate-of-increase limits, the major effect is the amount of excess costs that would not be paid.

We note that, under § 413.40(d)(3), an excluded hospital that continues to be paid under the TEFRA system and whose costs exceed 110 percent of its rate-of-increase limit receives its rate-of-increase limit plus the lesser of: (1) 50 percent of its reasonable costs in excess of 110 percent of the limit; or (2) 10 percent of its limit. In addition, under the various provisions set forth in § 413.40, hospitals can obtain payment adjustments for justifiable increases in operating costs that exceed the limit.

G. Quantitative Effects of the Proposed Policy Changes Under the IPPS for Operating Costs

1. Basis and Methodology of Estimates

In this proposed rule, we are announcing proposed policy changes and proposed payment rate updates for the IPPS for FY 2017 for operating costs of acute care hospitals. The proposed FY 2017 updates to the capital payments to acute care hospitals are discussed in section I.I. of this Appendix.

Based on the overall percentage change in payments per case estimated using our payment simulation model, we estimate that total FY 2017 operating payments would increase by 0.7 percent compared to FY 2016. In addition to the applicable percentage increase, this amount reflects the proposed FY 2017 recoupment adjustment for documentation and coding described in section II.D. of the preamble of this proposed rule of −1.5 percent to the IPPS national standardized amounts. This amount also reflects the proposed adjustment of (1/0.998) to permanently remove the 0.2 percent reduction and the proposed 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 related to the 2-midnight policy, which are discussed in section IV.O. of the preamble of this proposed rule. The impacts do not reflect changes in the number of hospital admissions or real case-mix intensity, which would also affect overall proposed payment changes.

We have prepared separate impact analyses of the proposed changes to each system. This section deals with the proposed changes to the operating inpatient prospective payment system for acute care hospitals. Our payment simulation model relies on the most recent available data to enable us to estimate the impacts on payments per case of certain changes in this proposed rule. However, there are other proposed changes for which we do not have data available that would allow us to estimate the payment impacts using this model. For those proposed changes, we have attempted to predict the payment impacts based upon our experience and other more limited data.

The data used in developing the quantitative analyses of proposed changes in payments per case presented in this section are taken from the FY 2015 MedPAR file and the most current Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the proposed changes to the operating PPS do not incorporate cost data, data from the most recently available hospital cost reports were used to categorize hospitals. Our analysis has several qualifications. First, in this analysis, we do not make adjustments for future changes in such variables as admissions, lengths of stay, or underlying growth in real case-mix. Second, due to the interdependent nature of the IPPS payment components, it is very difficult to precisely quantify the impact associated with each proposed change. Third, we use various data sources to categorize hospitals in the tables. In some cases, particularly the number of beds, there is a fair degree of variation in the data from the different sources. We have attempted to construct these variables with the best available source overall. However, for individual hospitals, some miscategorizations are possible.

Using cases from the FY 2015 MedPAR file, we simulate payments under the operating IPPS given various combinations of payment parameters. As described previously, Indian Health Service hospitals and hospitals in Maryland were excluded from the simulations. The proposed impact of payments under the capital IPPS, or the impact of payments for costs other than inpatient operating costs, are not analyzed in this section. Estimated payment impacts of the capital IPPS for FY 2017 are discussed in section I.I. of this Appendix.

We discuss the following proposed changes:

- The effects of the proposed application of the documentation and coding adjustment and the applicable percentage increase (including the proposed market basket update, the proposed multifactor productivity adjustment, and the applicable percentage reduction in accordance with the Affordable Care Act) to the standardized amount and hospital-specific rates.
- The effects of the proposed adjustment of (1/0.998) to permanently remove the 0.2 percent reduction and the proposed 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 related to the 2-midnight policy, as discussed in section IV.O. of the preamble of this proposed rule.
- The effects of the proposed changes to the relative weights and MS–DRG GROUPER.
- The effects of the proposed changes in hospitals' wage index values reflecting updated wage data from hospitals' cost reporting periods beginning during FY 2013, compared to the FY 2012 wage data, to calculate the FY 2017 wage index.
- The effects of the geographic reclassifications by the MGCRB (as of publication of this proposed rule) that would be effective for FY 2017.
- The effects of the proposed rural floor and imputed floor with the application of the proposed national budget neutrality factor to the wage index.
- The effects of the last year of the 3-year transition for hospitals that were located in an urban county that became rural under the new OMB delineations or hospitals that were deemed urban where the urban area became rural under the new OMB delineations.
- The effects of the proposed frontier State wage index adjustment under the statutory provision that requires that hospitals located in States that qualify as frontier States to not have a wage index less than 1.0. This provision is not budget neutral.
- The effects of the implementation of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. This provision is not budget neutral.
- The total estimated change in payments based on the proposed FY 2017 policies relative to payments based on FY 2016 policies that include the applicable percentage increase of 1.55 percent (or 2.8 percent market basket update with a proposed reduction of 0.5 percentage point for the multifactor productivity adjustment, and a 0.75 percentage point reduction, as required under the Affordable Care Act).

To illustrate the impact of the proposed FY 2017 changes, our analysis begins with a FY 2016 baseline simulation model using: The FY 2016 applicable percentage increase of 1.7 percent and the documentation and coding recoupment adjustment of −0.8 percent to the Federal standardized amount; the FY 2016 MS–DRG GROUPER (Version 33); the FY 2016 CBSA designations for hospitals based on the new OMB definitions; the FY 2016 wage index; and no MGCRB reclassifications. Outlier payments are set at

5.1 percent of total operating MS–DRG and outlier payments for modeling purposes.

Section 1886(b)(3)(B)(viii) of the Act, as added by section 5001(a) of Public Law 109–171, as amended by section 4102(b)(1)(A) of the ARRA (Pub. L. 111–5) and by section 3401(a)(2) of the Affordable Care Act (Pub. L. 111–148), provides that, for FY 2007 and each subsequent year through FY 2014, the update factor will include a reduction of 2.0 percentage points for any subsection (d) hospital that does not submit data on measures in a form and manner and at a time specified by the Secretary. Beginning in FY 2015, the reduction is one-quarter of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act, or one-quarter of the market basket update. Therefore, for FY 2017, we are proposing that hospitals that do not submit quality information under rules established by the Secretary and that are meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act would receive an applicable percentage increase of 0.85 percent. At the time that this impact was prepared, 90 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2016 because they failed the quality data submission process or did not choose to participate but are meaningful EHR users. For purposes of the simulations shown later in this section, we modeled the proposed payment changes for FY 2017 using a reduced update for these 90 hospitals.

For FY 2017, in accordance with section 1886(b)(3)(B)(ix) of the Act, a hospital that has been identified as not a meaningful EHR user would be subject to a reduction of three-quarters of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act. Therefore, for FY 2017, we are proposing that hospitals that are identified as not meaningful EHR users and do submit quality information under section 1886(b)(3)(B)(viii) of the Act would receive an applicable percentage increase of −0.55 percent. At the time that this impact analysis was prepared, 147 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2017 because they are identified as not meaningful EHR users that do submit quality information under section 1886(b)(3)(B)(viii) of the Act. For purposes of the simulations shown in this section, we modeled the proposed payment changes for FY 2017 using a reduced update for these 147 hospitals.

Hospitals that are identified as not meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act and also do not submit quality data under section 1886(b)(3)(B)(viii) of the Act would receive an applicable percentage increase of −1.25 percent, which reflects a one-quarter reduction of the market basket update for failure to submit quality data and a three-quarter reduction of the market basket update for being identified as not a meaningful EHR user. At the time that this impact was prepared, 30 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2017 because they are identified as not meaningful EHR users that do not submit quality data under section 1886(b)(3)(B)(viii) of the Act.

Each proposed policy change, statutory or otherwise, is then added incrementally to this baseline, finally arriving at an FY 2017 model incorporating all of the proposed changes. This simulation would allow us to isolate the effects of each proposed change.

Our final comparison illustrates the percent change in payments per case from FY 2016 to FY 2017. Three factors not discussed separately have significant impacts here. The first factor is the proposed update to the standardized amount. In accordance with section 1886(b)(3)(B)(i) of the Act, we are proposing to update the standardized amounts for FY 2017 using a proposed applicable percentage increase of 1.55 percent. This includes our forecasted IPPS operating hospital market basket increase of 2.8 percent with a reduction of 0.5 percentage point for the multifactor productivity adjustment and a 0.75 percentage point reduction as required under the Affordable Care Act. Hospitals that fail to comply with the quality data submission requirements and are meaningful EHR users would receive a proposed update of 0.85 percent. This update includes a reduction of one-quarter of the market basket update for failure to submit these data. Hospitals that do comply with the quality data submission requirements but are not meaningful EHR users would receive an update of −0.55 percent, which includes a reduction of three-quarters of the market basket update. Furthermore, hospitals that do not comply with the quality data submission requirements and also are not meaningful EHR users would receive an update of −1.25 percent. Under section 1886(b)(3)(B)(iv) of the Act, the update to the hospital-specific amounts for SCHs and MDHs also is equal to the applicable percentage increase, or 1.55 percent if the hospital submits quality data and is a meaningful EHR user.

A second significant factor that affects the proposed changes in hospitals' payments per case from FY 2016 to FY 2017 is the change in hospitals' geographic reclassification status from one year to the next. That is, payments may be reduced for hospitals reclassified in FY 2016 that are no longer reclassified in FY 2017. Conversely, payments may increase for hospitals not reclassified in FY 2016 that are reclassified in FY 2017.

A third significant factor is that we currently estimate that actual outlier payments during FY 2016 would be 5.3 percent of total MS–DRG payments. When the FY 2016 IPPS/LTCH PPS final rule was published, we projected FY 2016 outlier payments would be 5.1 percent of total MS–DRG plus outlier payments; the average standardized amounts were offset correspondingly. The effects of the higher than expected outlier payments during FY 2016 are reflected in the analyses in this section comparing our current estimates of FY 2016 payments per case to estimated FY 2017 payments per case (with outlier payments projected to equal 5.1 percent of total MS–DRG payments).

2. Analysis of Table I

Table I displays the results of our analysis of the proposed changes for FY 2017. The table categorizes hospitals by various geographic and special payment consideration groups to illustrate the varying impacts on different types of hospitals. The top row of the table shows the overall impact on the 3,330 acute care hospitals included in the analysis.

The next four rows of Table I contain hospitals categorized according to their geographic location: All urban, which is further divided into large urban and other urban; and rural. There are 2,512 hospitals located in urban areas included in our analysis. Among these, there are 1,378 hospitals located in large urban areas (populations over 1 million), and 1,134 hospitals in other urban areas (populations of 1 million or fewer). In addition, there are 818 hospitals in rural areas. The next two groupings are by bed-size categories, shown separately for urban and rural hospitals. The final groupings by geographic location are by census divisions, also shown separately for urban and rural hospitals.

The second part of Table I shows hospital groups based on hospitals' FY 2017 proposed payment classifications, including any reclassifications under section 1886(d)(10) of the Act. For example, the rows labeled urban, large urban, other urban, and rural show that the numbers of hospitals paid based on these categorizations after consideration of geographic reclassifications (including reclassifications under sections 1886(d)(8)(B) and 1886(d)(8)(E) of the Act that have implications for capital payments) are 2,455; 1,372; 1,083; and 875, respectively.

The next three groupings examine the impacts of the proposed changes on hospitals grouped by whether or not they have GME residency programs (teaching hospitals that receive an IME adjustment) or receive Medicare DSH payments, or some combination of these two adjustments. There are 2,275 nonteaching hospitals in our analysis, 804 teaching hospitals with fewer than 100 residents, and 251 teaching hospitals with 100 or more residents.

In the DSH categories, hospitals are grouped according to their DSH payment status, and whether they are considered urban or rural for DSH purposes. The next category groups together hospitals considered urban or rural, in terms of whether they receive the IME adjustment, the DSH adjustment, both, or neither.

The next three rows examine the impacts of the proposed changes on rural hospitals by special payment groups (SCHs, RRCs, and MDHs). There were 193 RRCs, 326 SCHs, 146 MDHs, 126 hospitals that are both SCHs and RRCs, and 15 hospitals that are both MDHs and RRCs.

The next series of groupings are based on the type of ownership and the hospital's Medicare utilization expressed as a percent of total patient days. These data were taken from the FY 2013 or FY 2012 Medicare cost reports.

The next two groupings concern the geographic reclassification status of hospitals. The first grouping displays all urban hospitals that were reclassified by the MGCRB for FY 2017. The second grouping shows the MGCRB rural reclassifications.

TABLE I—IMPACT ANALYSIS OF PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2017

	Number of hospitals[1]	Proposed hospital rate update and documentation and coding adjustment (1)[2]	Proposed FY 2017 weights and DRG changes with application of recalibration budget neutrality (2)[3]	Proposed FY 2017 wage data under new CBSA designations with application of wage budget neutrality (3)[4]	FY 2017 MGCRB reclassifications (4)[5]	Proposed rural and imputed floor with application of national rural and imputed floor budget neutrality (5)[6]	Proposed application of the frontier wage index and out-migration adjustment (6)[7]	All proposed FY 2017 changes (7)[8]
All Hospitals	3,330	0.9	0	0	0	0	0.1	0.7
By Geographic Location:								
Urban hospitals	2,512	0.8	0	0	−0.1	0	0.1	0.6
Large urban areas	1,378	0.8	0.1	0	−0.3	−0.1	0	0.6
Other urban areas	1,134	0.9	0	0	0.1	0.2	0.2	0.7
Rural hospitals	818	1.5	−0.4	0.1	1.4	−0.2	0.1	0.8
Bed Size (Urban):								
0–99 beds	656	0.8	−0.2	0.2	−0.5	0.1	0.2	0.7
100–199 beds	765	0.9	−0.2	0	0	0.3	0.2	0.5
200–299 beds	449	0.9	−0.1	−0.1	0.1	0	0.1	0.5
300–499 beds	429	0.9	0.1	0.1	−0.2	0	0.2	0.7
500 or more beds	213	0.8	0.2	−0.1	−0.2	−0.1	0	0.8
Bed Size (Rural):								
0–49 beds	320	1.3	−0.5	0.1	0.3	−0.2	0.3	0.6
50–99 beds	292	1.7	−0.6	0.1	0.8	−0.1	0.1	0.8
100–149 beds	119	1.5	−0.4	0	1.5	−0.2	0.2	0.6
150–199 beds	46	1.5	−0.2	0.1	1.7	−0.2	0	1.0
200 or more beds	41	1.5	−0.1	0.2	2.5	−0.2	0	1.2
Urban by Region:								
New England	116	0.7	0	−0.4	1.3	0.8	0	−0.6
Middle Atlantic	315	0.8	0.1	−0.3	0.5	−0.2	0.1	0.2
South Atlantic	406	0.9	0	−0.1	−0.4	−0.2	0.1	0.8
East North Central	390	0.8	0	0.1	−0.2	−0.3	0	1.1
East South Central	147	0.9	0	−0.2	−0.4	−0.3	0	1.0
West North Central	163	1	0.1	0	−0.7	−0.3	0.7	0.9
West South Central	384	0.8	0	0.3	−0.4	−0.3	0	1.2
Mountain	163	1	0	0.2	−0.4	0	0.2	0.7
Pacific	377	0.8	0	0.4	−0.4	1.1	0.1	0.4
Puerto Rico	51	0.8	0.1	−0.4	−0.9	0.2	0.1	0.3
Rural by Region:								
New England	21	1.2	−0.2	0.4	1.5	−0.2	0	1.2
Middle Atlantic	55	1.7	−0.4	0.1	0.6	−0.1	0.1	0.9
South Atlantic	127	1.4	−0.4	−0.1	2.5	−0.2	0.1	0.8
East North Central	115	1.6	−0.4	0	1	−0.1	0	0.9
East South Central	156	1	−0.3	0.4	2.1	−0.3	0.1	0.7
West North Central	99	2.1	−0.4	0	0.3	−0.1	0.3	1.0
West South Central	161	1.6	−0.5	0.2	1.6	−0.2	0.1	0.9
Mountain	60	1.6	−0.4	0.1	0.2	−0.1	0.1	0.7
Pacific	24	1.7	−0.5	−0.2	1.3	−0.1	0	0.8
By Payment Classification:								
Urban hospitals	2,455	0.8	0	0	−0.1	0	0.1	0.6
Large urban areas	1,372	0.8	0.1	0	−0.3	−0.1	0	0.6
Other urban areas	1,083	0.9	0	0	0.2	0.2	0.2	0.7
Rural areas	875	1.6	−0.4	0.1	1.1	−0.1	0.3	0.9
Teaching Status:								
Nonteaching	2,275	1	−0.2	0	0.2	0.1	0.1	0.6
Fewer than 100 residents	804	0.9	0	0	−0.1	0	0.2	0.7
100 or more residents	251	0.8	0.2	−0.1	−0.1	−0.2	0	0.8
Urban DSH:								
Non-DSH	597	0.9	0	−0.1	0.1	−0.1	0.1	0.5
100 or more beds	1,608	0.8	0.1	0	−0.1	0	0.1	0.7
Less than 100 beds	330	0.8	−0.3	0.1	−0.6	0.1	0.1	0.5
Rural DSH:								
SCH	266	2	−0.5	0.1	0	0	0	0.9
RRC	347	1.5	−0.3	0.1	1.5	−0.2	0.3	0.9
100 or more beds	33	0.8	−0.4	−0.1	2.9	−0.3	0.1	0.5
Less than 100 beds	149	0.7	−0.4	0.1	1.4	−0.3	0.5	0.2
Urban teaching and DSH:								
Both teaching and DSH	880	0.8	0.1	0	−0.2	−0.1	0.1	0.7
Teaching and no DSH	107	0.8	0	0	0.7	−0.1	0	0.2
No teaching and DSH	1,058	0.8	−0.1	0.1	0	0.2	0.1	0.5
No teaching and no DSH	410	0.8	0	−0.1	−0.3	0	0.1	0.7
Special Hospital Types:								
RRC	193	0.8	−0.1	0.2	2	−0.1	0.4	1.1
SCH	326	2	−0.3	−0.1	0	0	0	1.0
MDH	146	1.6	−0.6	0	0.5	−0.1	0.2	0.8
SCH and RRC	126	2	−0.3	0.1	0.4	−0.1	0	1.2
MDH and RRC	15	1.8	−0.5	−0.1	0.8	−0.1	0	1.3
Type of Ownership:								
Voluntary	1,914	0.9	0	0	0	0	0.1	0.7
Proprietary	858	0.9	0	0.1	0.1	0	0.1	0.8
Government	516	0.9	0	−0.2	−0.2	0.1	0.1	0.5

TABLE I—IMPACT ANALYSIS OF PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2017—Continued

	Number of hospitals[1]	Proposed hospital rate update and documentation and coding adjustment (1)[2]	Proposed FY 2017 weights and DRG changes with application of recalibration budget neutrality (2)[3]	Proposed FY 2017 wage data under new CBSA designations with application of wage budget neutrality (3)[4]	FY 2017 MGCRB reclassifications (4)[5]	Proposed rural and imputed floor with application of national rural and imputed floor budget neutrality (5)[6]	Proposed application of the frontier wage index and out-migration adjustment (6)[7]	All proposed FY 2017 changes (7)[8]
Medicare Utilization as a Percent of Inpatient Days:								
0–25	517	0.7	0.1	0	−0.4	0.1	0	0.7
25–50	2,128	0.9	0	0	0	0	0.1	0.7
50–65	546	1.1	−0.2	−0.1	0.6	0.1	0.1	0.5
Over 65	94	1.1	−0.3	0.3	−0.5	0.3	0.2	0.9
FY 2017 Reclassifications by the Medicare Geographic Classification Review Board:								
All Reclassified Hospitals	853	0.9	0	0	2.1	−0.1	0	0.6
Non-Reclassified Hospitals	2,477	0.9	0	0	−0.9	0	0.1	0.7
Urban Hospitals Reclassified	576	0.8	0	0	2	−0.1	0	0.5
Urban Nonreclassified Hospitals	1,879	0.8	0.1	0	−0.9	0.1	0.1	0.7
Rural Hospitals Reclassified Full Year	277	1.6	−0.3	0.1	2.3	−0.2	0	1.0
Rural Nonreclassified Hospitals Full Year	484	1.5	−0.5	0.2	−0.2	−0.1	0.3	0.7
All Section 401 Reclassified Hospitals:	57	1.7	−0.2	0.2	−0.4	0	1.2	1.0
Other Reclassified Hospitals (Section 1886(d)(8)(B))	57	1.2	−0.4	0.1	3	−0.3	0	0.6

[1] Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2015, and hospital cost report data are from reporting periods beginning in FY 2012 and FY 2013.

[2] This column displays the payment impact of the proposed hospital rate update and other proposed adjustments including the proposed 1.55 percent adjustment to the national standardized amount and hospital-specific rate (the estimated 2.8 percent market basket update reduced by the 0.5 percentage point for the proposed multifactor productivity adjustment and the 0.75 percentage point reduction under the Affordable Care Act), the −1.5 percent proposed documentation and coding adjustment to the national standardized amount and the proposed adjustment of (1/0.998) to permanently remove the −0.2 percent reduction, and the proposed 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 related to the 2-midnight policy.

[3] This column displays the payment impact of the proposed changes to the Version 34 GROUPER, the proposed changes to the relative weights and the recalibration of the MS–DRG weights based on FY 2015 MedPAR data in accordance with section 1886(d)(4)(C)(iii) of the Act. This column displays the application of the proposed recalibration budget neutrality factor of 0.999006 in accordance with section 1886(d)(4)(C)(iii) of the Act.

[4] This column displays the payment impact of the proposed update to wage index data using FY 2013 cost report data and the OMB labor market area delineations based on 2010 Decennial Census data. This column displays the payment impact of the application of the proposed wage budget neutrality factor, which is calculated separately from the proposed recalibration budget neutrality factor, and is calculated in accordance with section 1886(d)(3)(E)(i) of the Act. The proposed wage budget neutrality factor is 0.999785.

[5] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB) along with the effects of the continued implementation of the new OMB labor market area delineations on these reclassifications. The effects demonstrate the FY 2017 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2017. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the proposed geographic budget neutrality factor of 0.988816.

[6] This column displays the effects of the proposed rural and imputed floor based on the continued implementation of the new OMB labor market area delineations. The Affordable Care Act requires the rural floor budget neutrality adjustment to be 100 percent national level adjustment. The proposed rural floor budget neutrality factor (which includes the proposed imputed floor) applied to the wage index is 0.993806. This column also shows the effect of the 3-year transition for hospitals that were located in urban counties that became rural under the new OMB delineations or hospitals deemed urban where the urban area became rural under the new OMB delineations, with a proposed budget neutrality factor of 0.999999.

[7] This column shows the combined impact of the policy required under section 10324 of the Affordable Care Act that hospitals located in frontier States have a wage index no less than 1.0 and of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. These are non-budget neutral policies.

[8] This column shows the proposed changes in payments from FY 2016 to FY 2017. It reflects the impact of the proposed FY 2017 hospital update and the proposed adjustment for documentation and coding. It also reflects proposed changes in hospitals' reclassification status in FY 2017 compared to FY 2016. It incorporates all of the proposed changes displayed in Columns 1 through 6. The sum of these impacts may be different from the proposed percentage changes shown here due to rounding and interactive effects.

a. Effects of the Proposed Hospital Update, Documentation and Coding Adjustment, and Other Adjustments (Column 1)

As discussed in section IV.B. of the preamble of this proposed rule, this column includes the proposed hospital update, including the proposed 2.8 percent market basket update, the proposed reduction of 0.5 percentage point for the multifactor productivity adjustment, and the 0.75 percentage point reduction in accordance with the Affordable Care Act. In addition, as discussed in section II.D. of the preamble of this proposed rule, this column includes the proposed FY 2017 documentation and coding recoupment adjustment of −1.5 percent on the national standardized amount as part of the recoupment required by section 631 of the ATRA and, as discussed in section IV.O. of the preamble of this proposed rule, the proposed adjustment of (1/0.998) to permanently remove the 0.2 percent reduction and the proposed 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 related to the 2-midnight policy. As a result, we are proposing to make a 0.9 percent update to the national standardized amount. This column also includes the proposed 1.55 percent update to the hospital-specific rates which includes the proposed 2.8 percent market basket update, the proposed reduction of 0.5 percentage point for the multifactor productivity adjustment, the 0.75 percentage point reduction in accordance with the Affordable Care Act. In addition, this column includes the proposed adjustment to the hospital-specific rates of (1/0.998) to permanently remove the −0.2 percent reduction and the proposed 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016, which are discussed in section IV.O. of the preamble of this proposed rule. As a result, we are proposing to make a 2.35 percent update to the hospital-specific rates.

Overall, hospitals would experience a 0.9 percent increase in payments primarily due to the combined effects of the proposed hospital update and the proposed documentation and coding adjustment on the national standardized amount and the proposed hospital update to the hospital-specific rate as well as the proposed adjustment of (1/0.998) to permanently remove the −0.2 percent reduction and the proposed 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 related to the 2-midnight policy to both the national standardized amount and the hospital-specific rate. Hospitals that are paid under the hospital-specific rate, namely SCHs, would experience a 2.0 percent increase in payments; therefore, hospital categories with SCHs paid under the hospital-specific rate would experience increases in payments of more than 0.9 percent.

b. Effects of the Proposed Changes to the MS–DRG Reclassifications and Relative Cost-Based Weights With Recalibration Budget Neutrality (Column 2)

Column 2 shows the effects of the proposed changes to the MS–DRGs and relative weights with the application of the recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Consistent with section 1886(d)(4)(C)(iii) of the Act, we are calculating a recalibration budget neutrality factor to account for the changes in MS–DRGs and relative weights to ensure that the overall payment impact is budget neutral.

As discussed in section II.E. of the preamble of this proposed rule, the FY 2017 MS–DRG relative weights would be 100 percent cost-based and 100 percent MS–DRGs. For FY 2017, the MS–DRGs are calculated using the FY 2015 MedPAR data grouped to the Version 34 (FY 2017) MS–DRGs. The methodology to calculate the relative weights and the reclassification changes to the GROUPER are described in more detail in section II.G. of the preamble of this proposed rule.

The "All Hospitals" line in Column 2 indicates that proposed changes due to the MS–DRGs and relative weights would result in a 0.0 percent change in payments with the application of the proposed recalibration budget neutrality factor of 0.999006 on to the standardized amount. Hospital categories that generally treat more surgical cases than medical cases would experience increases in their payments under the relative weights. Rural hospitals would experience a 0.4 percent decrease in payments because rural hospitals tend to treat fewer surgical cases than medical cases, while teaching hospitals with more than 100 residents would experience an increase in payments by 0.2 percent as those hospitals treat more surgical cases than medical cases.

c. Effects of the Proposed Wage Index Changes (Column 3)

Column 3 shows the impact of updated wage data using FY 2013 cost report data, with the application of the wage budget neutrality factor. The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on the Core Based Statistical Areas (CBSAs) established by OMB. The current statistical standards used in FY 2017 are based on OMB standards published on February 28, 2013 (75 FR 37246 and 37252), and 2010 Decennial Census data (OMB Bulletin No. 13–01). (We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) for a full discussion on our adoption of the OMB labor market area delineations based on the 2010 Decennial Census data, effective beginning with the FY 2015 IPPS wage index).

Section 1886(d)(3)(E) of the Act requires that, beginning October 1, 1993, we annually update the wage data used to calculate the wage index. In accordance with this requirement, the proposed wage index for acute care hospitals for FY 2017 is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2012 and before October 1, 2013. The estimated impact of the updated wage data using the FY 2013 cost report data and the OMB labor market area delineations on hospital payments is isolated in Column 3 by holding the other payment parameters constant in this simulation. That is, Column 3 shows the percentage change in payments when going from a model using the FY 2016 wage index, based on FY 2012 wage data, the labor-related share of 69.6 percent, under the OMB delineations and having a 100-percent occupational mix adjustment applied, to a model using the FY 2017 pre-reclassification wage index based on FY 2013 wage data with the labor-related share of 69.6 percent, under the OMB delineations, also having a 100-percent occupational mix adjustment applied, while holding other proposed payment parameters such as use of the Version 34 MS–DRG GROUPER constant. The proposed FY 2017 occupational mix adjustment is based on the CY 2013 occupational mix survey.

In addition, the column shows the impact of the proposed application of the wage budget neutrality to the national standardized amount. In FY 2010, we began calculating separate wage budget neutrality and recalibration budget neutrality factors, in accordance with section 1886(d)(3)(E) of the Act, which specifies that budget neutrality to account for wage index changes or updates made under that subparagraph must be made without regard to the 62 percent labor-related share guaranteed under section 1886(d)(3)(E)(ii) of the Act. Therefore, for FY 2017, we are proposing to calculate the wage budget neutrality factor to ensure that payments under updated wage data and the labor-related share of 69.6 percent are budget neutral without regard to the lower labor-related share of 62 percent applied to hospitals with a wage index less than or equal to 1.0. In other words, the wage budget neutrality is calculated under the assumption that all hospitals receive the higher labor-related share of the standardized amount. The proposed FY 2017 wage budget neutrality factor is 0.999785, and the overall payment change is 0.0 percent.

Column 3 shows the impacts of updating the wage data using FY 2013 cost reports. Overall, the new wage data and the labor-related share, combined with the proposed wage budget neutrality adjustment, would lead to no change for all hospitals as shown in Column 3.

In looking at the wage data itself, the proposed national average hourly wage would increase 1.02 percent compared to FY 2016. Therefore, the only manner in which to maintain or exceed the previous year's wage index was to match or exceed the national 1.02 percent increase in average hourly wage. Of the 3,303 hospitals with wage data for both FYs 2016 and 2017, 1.634 or 49.5 percent would experience an average hourly wage increase of 1.02 percent or more.

The following chart compares the shifts in wage index values for hospitals due to proposed changes in the average hourly wage data for FY 2017 relative to FY 2016. Among urban hospitals, 5 would experience a decrease of 10 percent or more, and 14 urban hospitals would experience an increase of 10 percent or more. One hundred and thirty-nine urban hospitals would experience an increase or decrease of at least 5 percent or more but less than 10 percent. Among rural hospitals, 9 would experience an increase of at least 5 percent but less than 10 percent, but no rural hospitals would experience a decrease of greater than or equal to 5 percent but less than 10 percent. No rural hospital would experience increases of 10 percent or more, but 2 rural hospitals would experience decreases of 10 percent or more. However, 794 rural hospitals would experience increases or decreases of less than 5 percent, while 2,340 urban hospitals would experience increases or decreases of less than 5 percent. No urban hospital and no rural hospital would experience no change to their wage index. These figures reflect proposed changes in the "pre-reclassified, occupational mix-adjusted wage index," that is, the proposed wage index before the application of proposed geographic reclassification, the proposed rural and imputed floors, the proposed out-migration adjustment, and other proposed wage index exceptions and adjustments. (We refer readers to sections III.G. through III.L. of the preamble of this proposed rule for a complete discussion of the exceptions and adjustments to the wage index.) We note that the proposed "post-reclassified wage index" or proposed "payment wage index," which is the proposed wage index that includes all such exceptions and adjustments (as reflected in Tables 2 and 3 associated with this proposed rule, which are available via the Internet on the CMS Web site) is used to adjust the labor-related share of a hospital's standardized amount, either 69.6 percent or 62 percent, depending upon whether a hospital's wage index is greater than 1.0 or less than or equal to 1.0. Therefore, the proposed pre-reclassified wage index figures in the following chart may illustrate a somewhat larger or smaller change than would occur in a hospital's proposed payment wage index and total payment.

The following chart shows the projected impact of proposed changes in the area wage index values for urban and rural hospitals.

PROPOSED FY 2017 PERCENTAGE CHANGE IN AREA WAGE INDEX VALUES

	Number of hospitals	
	Urban	Rural
Increase 10 percent or more	14	0
Increase greater than or equal to 5 percent and less than 10 percent	88	9
Increase or decrease less than 5 percent	2,340	794
Decrease greater than or equal to 5 percent and less than 10 percent	51	0
Decrease 10 percent or more	5	2
Unchanged	0	0

d. Effects of MGCRB Reclassifications (Column 4)

Our impact analysis to this point has assumed acute care hospitals are paid on the basis of their actual geographic location (with the exception of ongoing policies that provide that certain hospitals receive payments on bases other than where they are geographically located). The proposed changes in Column 4 reflect the per case payment impact of moving from this baseline to a simulation incorporating the MGCRB decisions for FY 2017.

By spring of each year, the MGCRB makes reclassification determinations that would be effective for the next fiscal year, which begins on October 1. The MGCRB may approve a hospital's reclassification request for the purpose of using another area's wage index value. Hospitals may appeal denials of MGCRB decisions to the CMS Administrator. Further, hospitals have 45 days from publication of the IPPS proposed rule in the **Federal Register** to decide whether to withdraw or terminate an approved geographic reclassification for the following year.

The overall effect of geographic reclassification is required by section 1886(d)(8)(D) of the Act to be budget neutral. Therefore, for purposes of this impact analysis, we are proposing to apply an adjustment of 0.988816 to ensure that the effects of the reclassifications under section 1886(d)(10) of the Act are budget neutral (section II.A. of the Addendum to this proposed rule). Geographic reclassification generally benefits hospitals in rural areas. We estimate that the geographic reclassification would increase payments to rural hospitals by an average of 1.4 percent. By region, all the rural hospital categories will experience increases in payments due to MGCRB reclassifications.

New Table 2 listed in section VI. of the Addendum to this proposed rule and available via the Internet on the CMS Web site reflects the proposed reclassifications for FY 2017.

e. Effects of the Proposed Rural Floor and Imputed Floor, Including Application of National Budget Neutrality (Column 5)

As discussed in section III.B. of the preamble of the FY 2009 IPPS final rule, the FY 2010 IPPS/RY 2010 LTCH PPS final rule, the FYs 2011, 2012, 2013, 2014, 2015, 2016 IPPS/LTCH PPS final rules, and this proposed rule, section 4410 of Public Law 105–33 established the rural floor by requiring that the wage index for a hospital in any urban area cannot be less than the wage index received by rural hospitals in the same State. We would apply a uniform budget neutrality adjustment to the wage index. The imputed floor, which is also included in the calculation of the budget neutrality adjustment to the wage index, was extended in FY 2012 for 2 additional years and in FY 2014 and FY 2015 for 1 additional year. Prior to FY 2013, only urban hospitals in New Jersey received the imputed floor. As discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53369), we established an alternative temporary methodology for the imputed floor, which resulted in an imputed floor for Rhode Island for FY 2013. For FY 2014 and FY 2015, we extended the imputed rural floor, as calculated under the original methodology and the alternative methodology. Due to the adoption of the new OMB labor market area delineations in FY 2015, the State of Delaware also became an all-urban State and thus eligible for an imputed floor. For FY 2016, we extended the imputed floor for 1 year, as calculated under the original methodology and the alternative methodology, through September 30, 2016. For FY 2017, we are proposing to extend the imputed rural floor for 1 year, as calculated under the original methodology and the alternative methodology, through September 20, 2017. As a result, New Jersey, Rhode Island, and Delaware would be able to receive an imputed floor through September 30, 2017. In New Jersey, 20 out of 64 hospitals would receive the imputed floor, and 10 out of 11 hospitals in Rhode Island would receive the imputed floor for FY 2017. For FY 2017, no hospitals would benefit from the imputed floor in Delaware because the CBSA wage index for each CBSA in Delaware under the new OMB delineations is equal to or higher than the imputed rural floor.

The Affordable Care Act requires that we apply one rural floor budget neutrality factor to the wage index nationally, and the imputed floor is part of the rural floor budget neutrality factor applied to the wage index nationally. We have calculated a proposed FY 2017 rural floor budget neutrality factor to be applied to the wage index of 0.993806, which would reduce wage indexes by 0.62 percent.

Column 5 shows the projected impact of the proposed rural floor and imputed floor with the national rural floor budget neutrality factor applied to the wage index based on the OMB labor market area delineations. The column compares the proposed post-reclassification FY 2017 wage index of providers before the proposed rural floor and imputed floor adjustment and the proposed post-reclassification FY 2017 wage index of providers with the proposed rural floor and imputed floor adjustment based on the OMB labor market area delineations. Only urban hospitals can benefit from the rural and imputed floors. Because the provision is budget neutral, all other hospitals (that is, all rural hospitals and those urban hospitals to which the adjustment is not made) would experience a decrease in payments due to the budget neutrality adjustment that is applied nationally to their wage index.

We estimate that 401 hospitals would benefit from the proposed rural and imputed floors in FY 2017, while the remaining 2,929 IPPS hospitals in our model would have their wage index reduced by the rural floor budget neutrality adjustment of 0.993806 (or 0.62 percent). We project that, in aggregate, rural hospitals would experience a 0.2 percent decrease in payments as a result of the application of the proposed rural floor budget neutrality because the rural hospitals do not benefit from the rural floor, but have their wage indexes downwardly adjusted to ensure that the application of the rural floor is budget neutral overall. We project hospitals located in urban areas would experience no change in payments because increases in payments by hospitals benefitting from the rural floor offset decreases in payments by nonrural floor urban hospitals whose wage index is downwardly adjusted by the rural floor budget neutrality factor. Urban hospitals in the New England region would experience a 0.8 percent increase in payments primarily due to the application of the proposed rural floor in Massachusetts and the proposed imputed floor in Rhode Island. Fifteen urban providers in Massachusetts are expected to receive the proposed rural floor wage index value, including the rural floor budget neutrality of 0.993806, increasing payments overall to Massachusetts by an estimated $25 million. We estimate that Massachusetts hospitals would receive approximately a 0.8 percent increase in IPPS payments due to the application of the proposed rural floor in FY 2017.

Urban Puerto Rico hospitals are expected to experience a 0.2 percent increase in payments as a result of the application of the proposed rural floor budget neutrality factor, of 0.993806 or 0.62 percent, to the proposed rural floor wage index.

There are 20 hospitals out of the 64 hospitals in New Jersey that would benefit from the proposed extension of the imputed floor and would receive the imputed floor wage index value under the OMB labor market area delineations, including the rural floor budget neutrality of 0.993806, which we estimate would increase payments to those imputed floor hospitals by $20 million (overall, the State would receive an increase of $8 million in payments due to the other hospitals in the State that would experience decreases in payments due to the proposed rural floor budget neutrality adjustment). Ten hospitals out of the 11 hospitals in Rhode Island would benefit from the proposed imputed rural floor calculated under the alternative methodology and would receive an additional $18 million. While some hospitals in Delaware are geographically located in CBSAs that are assigned the imputed floor, none of these hospitals benefit from the imputed floor because they are reclassifying to CBSAs with a higher wage index than the imputed floor.

Column 5 also shows the projected effects of the last year of the 3-year hold harmless provision for hospitals that were located in an urban county that became rural under the new OMB delineations or hospitals deemed urban where the urban area became rural under the new OMB delineations. As discussed in section III.G.2. of the preamble of this proposed rule, under this transition, hospitals that were located in an urban county that became rural under the new OMB delineations will generally be assigned the urban wage index value of the CBSA in which they are physically located in FY 2014 for a period of 3 fiscal years (that is, FYs 2015, 2016, and 2017). In addition, as discussed in section III.G.3. of the preamble of this proposed rule, under this transition, hospitals that were deemed urban where the urban area became rural under the new OMB delineations will generally be assigned the area wage index value of hospitals reclassified to the urban CBSA (that is, the attaching wage index, if applicable) to which they were designated in FY 2014. For FY 2017, we are applying the 3-year transition wage index adjustments in a budget neutral manner, with a budget neutrality factor of 0.999999.

In response to a public comment addressed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51593), we are providing the payment impact of the proposed rural floor and imputed floor with budget neutrality at the State level. Column 1 of the following table displays the number of IPPS hospitals located in each State. Column 2 displays the number of hospitals in each State that would receive the proposed rural floor or imputed floor wage index for FY 2017. Column 3 displays the percentage of total payments each State would receive or contribute to fund the rural floor and imputed floor with national budget neutrality. The column compares the proposed post-reclassification FY 2017 wage index of providers before the proposed rural floor and imputed floor adjustment and the proposed post-reclassification FY 2017 wage index of providers with the proposed rural floor and imputed floor adjustment. Column 4 displays the estimated payment amount that each State would gain or lose due to the application of the proposed rural floor and imputed floor with national budget neutrality.

PROPOSED FY 2017 IPPS ESTIMATED PAYMENTS DUE TO RURAL AND IMPUTED FLOOR WITH NATIONAL BUDGET NEUTRALITY

State	Number of hospitals (1)	Number of hospitals that will receive the rural floor or imputed floor (2)	Proposed percent change in payments due to application of rural floor and imputed floor with budget neutrality (3)	Proposed difference (in millions) (4)
Alabama	83	6	−0.3	$−4.43
Alaska	6	1	−0.2	−0.34
Arizona	57	7	−0.1	−1.55
Arkansas	44	0	−0.3	−3.07
California	300	185	1.4	139.3
Colorado	48	3	0.3	3.57
Connecticut	31	13	0	0.29
Delaware	6	0	−0.4	−1.64
Washington, DC	7	0	−0.3	−1.62
Florida	171	15	−0.2	−11.11
Georgia	105	0	−0.3	−7.76
Hawaii	12	0	−0.3	−0.76
Idaho	14	0	−0.2	−0.74
Illinois	126	3	−0.3	−14.43
Indiana	89	0	−0.3	−8.24
Iowa	35	0	−0.3	−2.83
Kansas	53	0	−0.3	−2.5
Kentucky	65	0	−0.3	−4.71
Louisiana	95	0	−0.3	−4.19
Maine	18	0	−0.3	−1.53
Massachusetts	58	15	0.8	25.4
Michigan	95	0	−0.3	−14.07
Minnesota	49	0	−0.2	−5.06
Mississippi	62	0	−0.3	−3.08
Missouri	75	2	−0.3	−6.19
Montana	12	4	0.3	0.96
Nebraska	26	0	−0.2	−1.67
Nevada	24	3	−0.1	−0.79
New Hampshire	13	9	0.4	2.24
New Jersey	64	20	0.2	7.84
New Mexico	25	0	−0.2	−0.88
New York	154	21	−0.3	−20.52
North Carolina	84	4	−0.2	−5.88
North Dakota	6	1	−0.2	−0.57

PROPOSED FY 2017 IPPS ESTIMATED PAYMENTS DUE TO RURAL AND IMPUTED FLOOR WITH NATIONAL BUDGET NEUTRALITY—Continued

State	Number of hospitals (1)	Number of hospitals that will receive the rural floor or imputed floor (2)	Proposed percent change in payments due to application of rural floor and imputed floor with budget neutrality (3)	Proposed difference (in millions) (4)
Ohio	130	8	-0.3	-9.5
Oklahoma	86	2	-0.3	-3.53
Oregon	34	2	-0.3	-3.1
Pennsylvania	152	5	-0.3	-15.88
Puerto Rico	51	12	0.2	0.26
Rhode Island	11	10	4.8	18.11
South Carolina	56	5	-0.1	-0.99
South Dakota	18	0	-0.2	-0.67
Tennessee	93	20	-0.2	-5.59
Texas	320	1	-0.3	-20.35
Utah	33	1	-0.3	-1.33
Vermont	6	0	-0.2	-0.39
Virginia	75	1	-0.2	-6.29
Washington	49	8	0.2	4.38
West Virginia	29	2	-0.2	-1.21
Wisconsin	65	12	-0.2	-2.85
Wyoming	10	0	-0.1	-0.15

f. Effects of the Application of the Proposed Frontier State Wage Index and Out-Migration Adjustment (Column 6)

This column shows the combined effects of the application of section 10324(a) of the Affordable Care Act, which requires that we establish a minimum post-reclassified wage-index of 1.00 for all hospitals located in "frontier States," and the effects of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. These two wage index provisions are not budget neutral and increase payments overall by 0.1 percent compared to the provisions not being in effect.

The term "frontier States" is defined in the statute as States in which at least 50 percent of counties have a population density less than 6 persons per square mile. Based on these criteria, 5 States (Montana, Nevada, North Dakota, South Dakota, and Wyoming) are considered frontier States and 50 hospitals located in those States will receive a frontier wage index of 1.0000. Overall, this provision is not budget neutral and is estimated to increase IPPS operating payments by approximately $56 million. Rural and urban hospitals located in the West North Central region would experience an increase in payments by 0.3 and 0.7 percent, respectively, because many of the hospitals located in this region are frontier State hospitals.

In addition, section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. Hospitals located in counties that qualify for the payment adjustment are to receive an increase in the wage index that is equal to a weighted average of the difference between the wage index of the resident county, post-reclassification and the higher wage index work area(s), weighted by the overall percentage of workers who are employed in an area with a higher wage index. There are an estimated 249 providers that would receive the out-migration wage adjustment in FY 2017. Rural hospitals generally qualify for the adjustment, resulting in a 0.1 percent increase in payments. This provision appears to benefit section 401 hospitals and RRCs in that they would experience a 1.2 percent and 0.4 percent increase in payments, respectively. This out-migration wage adjustment also is not budget neutral, and we estimate the impact of these providers receiving the out-migration increase would be approximately $31 million.

g. Effects of All FY 2017 Changes (Column 7)

Column 7 shows our estimate of the proposed changes in payments per discharge from FY 2016 and FY 2017, resulting from all proposed changes reflected in this proposed rule for FY 2017. It includes combined effects of the previous columns in the table.

The proposed average increase in payments under the IPPS for all hospitals is approximately 0.7 percent for FY 2017 relative to FY 2016. This column includes the proposed annual hospital update of 1.55 percent to the national standardized amount. This proposed annual hospital update includes the 2.8 percent market basket update, the proposed reduction of 0.5 percentage point for the multifactor productivity adjustment, and the 0.75 percentage point reduction under section 3401 of the Affordable Care Act. As discussed in section II.D. of the preamble of this proposed rule, this column also includes the proposed FY 2017 documentation and coding recoupment adjustment of -1.5 percent on the national standardized amount as part of the recoupment required under section 631 of the ATRA. In addition, this column includes the proposed adjustment of (1/0.998) to permanently remove the 0.2 percent reduction, and the proposed 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 related to the 2-midnight policy, which are discussed in section IV.O. of the preamble of this proposed rule. Hospitals paid under the hospital-specific rate would receive a 1.55 percent proposed hospital update in addition to the proposed adjustment of (1/0.998) to permanently remove the 0.2 percent reduction, and the proposed 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 previously described. As described in Column 1, the proposed annual hospital update with the proposed documentation and coding recoupment adjustment for hospitals paid under the national standardized amount, the proposed adjustment of (1/0.998) to permanently remove the 0.2 percent reduction and the proposed 1.006 temporary adjustment to address the effects of the 0.2 percent reduction in effect for FYs 2014 through 2016 for hospitals paid under the national standardized amount and hospitals paid under the hospital-specific rates, which are discussed in section IV.O. of the preamble of this proposed rule, combined with the proposed annual hospital update for hospitals paid under the hospital-specific rates would result in a 0.7 percent increase in payments in FY 2017 relative to FY 2016. The impact of moving from our estimate of FY 2016 outlier payments, 5.3 percent, to the proposed estimate of FY 2017 outlier payments, 5.1 percent, would result in a decrease of 0.2 percent in FY 2017 payments relative to FY 2016. There also might be interactive effects among the various factors comprising the payment system that we are not able to isolate. For these reasons, the values in Column 7 may not equal the sum of the estimated percentage changes described previously.

Overall payments to hospitals paid under the IPPS due to the proposed applicable percentage increase and proposed changes to policies related to MS–DRGs, geographic adjustments, and outliers are estimated to increase by 0.7 percent for FY 2017. Hospitals in urban areas would experience a 0.6 percent increase in payments per discharge in FY 2017 compared to FY 2016. Hospital payments per discharge in rural areas are estimated to increase by 0.8 percent in FY 2017.

3. Impact Analysis of Table II

Table II presents the projected impact of the proposed changes for FY 2017 for urban and rural hospitals and for the different categories of hospitals shown in Table I. It compares the estimated average payments per discharge for FY 2016 with the proposed estimated average payments per discharge for FY 2017, as calculated under our models. Therefore, this table presents, in terms of the average dollar amounts paid per discharge, the combined effects of the proposed changes presented in Table I. The proposed estimated percentage changes shown in the last column of Table II equal the estimated percentage changes in average payments per discharge from Column 7 of Table I.

TABLE II—IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2017 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM

[Payments per discharge]

	Number of hospitals (1)	Estimated average FY 2016 payment per discharge (2)	Estimated average FY 2017 payment per discharge (3)	Proposed FY 2017 changes (4)
All Hospitals	3,330	11,524	11,599	0.7
By Geographic Location:				
Urban hospitals	2,512	11,869	11,944	0.6
Large urban areas	1,378	12,658	12,729	0.6
Other urban areas	1,134	10,924	11,004	0.7
Rural hospitals	818	8,614	8,686	0.8
Bed Size (Urban):				
0–99 beds	656	9,393	9,462	0.7
100–199 beds	765	10,006	10,052	0.5
200–299 beds	449	10,758	10,807	0.5
300–499 beds	429	12,068	12,153	0.7
500 or more beds	213	14,591	14,703	0.8
Bed Size (Rural):				
0–49 beds	320	7,187	7,230	0.6
50–99 beds	292	8,214	8,278	0.8
100–149 beds	119	8,457	8,506	0.6
150–199 beds	46	9,263	9,359	1.0
200 or more beds	41	10,175	10,295	1.2
Urban by Region:				
New England	116	12,947	12,870	−0.6
Middle Atlantic	315	13,445	13,469	0.2
South Atlantic	406	10,494	10,574	0.8
East North Central	390	11,167	11,290	1.1
East South Central	147	10,022	10,123	1.0
West North Central	163	11,589	11,694	0.9
West South Central	384	10,688	10,812	1.2
Mountain	163	12,273	12,361	0.7
Pacific	377	15,279	15,336	0.4
Puerto Rico	51	8,409	8,432	0.3
Rural by Region:				
New England	21	11,758	11,897	1.2
Middle Atlantic	55	8,646	8,726	0.9
South Atlantic	127	8,059	8,120	0.8
East North Central	115	8,947	9,023	0.9
East South Central	156	7,642	7,694	0.7
West North Central	99	9,464	9,555	1.0
West South Central	161	7,254	7,321	0.9
Mountain	60	10,142	10,214	0.7
Pacific	24	11,976	12,066	0.8
By Payment Classification:				
Urban hospitals	2,455	11,888	11,963	0.6
Large urban areas	1,372	12,664	12,735	0.6
Other urban areas	1,083	10,926	11,006	0.7
Rural areas	875	8,890	8,967	0.9
Teaching Status:				
Nonteaching	2,275	9,593	9,649	0.6
Fewer than 100 residents	804	11,122	11,194	0.7
100 or more residents	251	16,697	16,821	0.8
Urban DSH:				
Non-DSH	597	10,104	10,156	0.5

TABLE II—IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2017 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM—Continued

[Payments per discharge]

	Number of hospitals (1)	Estimated average FY 2016 payment per discharge (2)	Estimated average FY 2017 payment per discharge (3)	Proposed FY 2017 changes (4)
100 or more beds	1,608	12,247	12,327	0.7
Less than 100 beds	330	8,718	8,759	0.5
Rural DSH:				
SCH	266	9,218	9,299	0.9
RRC	347	9,200	9,286	0.9
100 or more beds	33	7,070	7,102	0.5
Less than 100 beds	149	6,783	6,798	0.2
Urban teaching and DSH:				
Both teaching and DSH	880	13,362	13,456	0.7
Teaching and no DSH	107	11,418	11,438	0.2
No teaching and DSH	1,058	10,009	10,061	0.5
No teaching and no DSH	410	9,519	9,585	0.7
Special Hospital Types:				
RRC	193	9,673	9,782	1.1
SCH	326	10,357	10,459	1.0
MDH	146	7,202	7,262	0.8
SCH and RRC	126	10,814	10,940	1.2
MDH and RRC	15	9,216	9,334	1.3
Type of Ownership:				
Voluntary	1,914	11,704	11,781	0.7
Proprietary	858	10,110	10,188	0.8
Government	516	12,474	12,532	0.5
Medicare Utilization as a Percent of Inpatient Days:				
0–25	517	14,964	15,062	0.7
25–50	2,128	11,446	11,523	0.7
50–65	546	9,341	9,387	0.5
Over 65	94	6,966	7,025	0.9
FY 2017 Reclassifications by the Medicare Geographic Classification Review Board:				
All Reclassified Hospitals	853	11,571	11,641	0.6
Non-Reclassified Hospitals	2,477	11,504	11,581	0.7
Urban Hospitals Reclassified	576	12,191	12,256	0.5
Urban Nonreclassified Hospitals	1,879	11,774	11,852	0.7
Rural Hospitals Reclassified Full Year	277	8,994	9,080	1.0
Rural Nonreclassified Hospitals Full Year	484	8,193	8,250	0.7
All Section 401 Reclassified Hospitals:	57	10,782	10,892	1.0
Other Reclassified Hospitals (Section 1886(d)(8)(B))	57	7,949	7,998	0.6

H. Effects of Other Proposed Policy Changes

In addition to those proposed policy changes discussed previously that we are able to model using our IPPS payment simulation model, we are proposing to make various other changes in this proposed rule. Generally, we have limited or no specific data available with which to estimate the impacts of these proposed changes. Our estimates of the likely impacts associated with these other proposed changes are discussed in this section.

1. Effects of Proposed Policy Relating to New Medical Service and Technology Add-On Payments

In section II.H. of the preamble to this proposed rule, we discuss nine technologies for which we received applications for add-on payments for new medical services and technologies for FY 2017, as well as the status of the new technologies that were approved to receive new technology add-on payments in FY 2016. We note that one applicant withdraw its application prior to the issuance of this proposed rule. As explained in the preamble to this proposed rule, add-on payments for new medical services and technologies under section 1886(d)(5)(K) of the Act are not required to be budget neutral. As discussed in section II.H.5. of the preamble of this proposed rule, we have not yet determined whether any of these nine technologies for which we received applications for consideration for new technology add-on payments for FY 2017 will meet the specified criteria. Consequently, it is premature to estimate the potential payment impact of these nine technologies for any potential new technology add-on payments for FY 2017. We note that if any of the nine technologies are found to be eligible for new technology add-on payments for FY 2017, in the FY 2017 IPPS/LTCH PPS final rule, we would discuss the estimated payment impact for FY 2017.

In section II.H.4. of the preamble of this proposed rule, we are proposing to discontinue new technology add-on payments for the Argus® II Retinal Prosthesis System, Kcentra™, the MitraClip® System, and the Responsive Neurostimulator (RNS®) for FY 2017 because these technologies will have been on the U.S. market for 3 years. We also are proposing to continue to make new technology add-on payments for the CardioMEMS™ HF (Heart Failure) Monitoring System, Blinatumomab (BLINCYTO™), and the LUTONIX® Drug Coated Balloon (DCB) Percutaneous Transluminal Angioplasty (PTA) and IN.PACT™ Admiral™ Pacliaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter in FY 2017 because these technologies are still considered new. We note that new technology add-on payments for each case are limited to the lesser of (1) 50 percent of the costs of the new technology or (2) 50 percent of the amount by which the costs of the case exceed the standard MS–DRG payment for the case. Because it is difficult to predict the actual new technology add-on payment for each case, our estimates below are based on the increase in new technology add-on payments for FY 2017 as if every claim that would qualify for a new technology add-on payment would receive the maximum add-on payment. For the CardioMEMS™ HF Monitoring System, based on the applicant's estimate from FY 2015, we currently estimate that new technology add-on payments for the CardioMEMS™ HF Monitoring System will increase overall FY 2017 payments by $11,315,625. Based on the applicant's estimate for FY 2016, we currently estimate that new technology add-on payments for BLINCYTO™ will increase overall FY 2017 payments by $4,593,034 (maximum add-on payment of $27,017.85 * 170 patients). Based on the weighted cost average for FY 2016 described in the FY 2016 IPPS/LTCH final rule (80 FR 49469 through 49470), we currently estimate that new technology add-on payments for the LUTONIX® DCB PTA and IN.PACT™ Admiral™ Pacliaxel Coated PTA Balloon Catheter will increase overall FY 2017 payments by $36,120,735 (maximum add-on payment of $1,035.72 * 8,875 patients for LUTONIX® DCB PTA Balloon Catheter; maximum add-on payment of $1,035.72 * 26,000 patients for IN.PACT™ Admiral™ Pacliaxel Coated PTA Balloon Catheter).

2. Effects of the Proposed Changes to Medicare DSH Payments for FY 2017

As discussed in section IV.F. of the preamble of this proposed rule, under section 3133 of the Affordable Care Act, hospitals that are eligible to receive Medicare DSH payments will receive 25 percent of the amount they previously would have received under the former statutory formula for Medicare DSH payments. The remainder, equal to an estimate of 75 percent of what formerly would have been paid as Medicare DSH payments (Factor 1), reduced to reflect changes in the percentage of individuals under age 65 who are uninsured and additional statutory adjustments (Factor 2), is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. Each hospital eligible for Medicare DSH payments will receive an additional payment based on its estimated share of the total amount of uncompensated care for all hospitals eligible for Medicare DSH payments. The uncompensated care payment methodology has redistributive effects based on the proportion of a hospital's uncompensated care relative to the uncompensated care for all hospitals eligible for Medicare DSH payments (Factor 3). For FY 2017, because we are proposing to continue to use low-income insured patient days as a proxy for uncompensated care, the uncompensated care payment methodology has redistributive effects based on the proportion of a hospital's low-income insured patient days (sum of Medicaid patient days and Medicare SSI patient days) relative to the low-income insured patient days for all hospitals eligible for DSH payments. The reduction to Medicare DSH payments under section 3133 of the Affordable Care Act is not budget neutral.

In this proposed rule, we are proposing to establish the overall amount available to be distributed as uncompensated care payments to DSH eligible hospitals, which for FY 2017 is $6,054,458,492.68, or 75 percent of what otherwise would have been paid for Medicare DSH payment adjustments adjusted by a proposed Factor 2 of 56.74 percent. For FY 2016, the amount available to be distributed for uncompensated care was $6,406,145,534.04, or 75 percent of what otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 63.69 percent. To calculate Factor 3 for FY 2017, we are proposing to use an average of data computed using Medicaid days from hospitals' 2011, 2012, and 2013 cost reports, Medicaid days from 2011 and 2012 cost report data submitted to CMS by IHS hospitals, and SSI days from the FY 2012, FY 2013, and FY 2014 SSI ratios. That is, for each hospital we are proposing to calculate an individual Factor 3 for cost reporting periods beginning during FYs 2011, 2012, and 2013, sum the individual amounts, and divide the sum by three in order to calculate an average Factor 3 for the hospital.

The FY 2017 proposal to use data on low-income insured days from 3 years of cost reports to determine Factor 3, as described earlier, is in contrast to the methodology used in FY 2016, when we used Medicaid days from the more recent of a hospital's full year 2012 *or* 2011 cost report from the March 2015 update of the HCRIS database, Medicaid days from 2012 cost report data submitted to CMS by IHS hospitals, and SSI days from the FY 2013 SSI ratios to calculate Factor 3. In addition, as explained in section IV.F. of the preamble of this proposed rule, we are proposing to make two additional modifications to the Factor 3 methodology: (1) To create proxy Medicare SSI values for Puerto Rico hospitals and (2) to include all hospitals' cost reports that begin during FYs 2011, 2012, and 2013, even in the instance where a hospital has more than one cost report beginning during a given fiscal year. Because residents of Puerto Rico are not eligible for SSI benefits, we are proposing to impute a Medicare SSI value for each Puerto Rico hospital equal to 14 percent of its Medicaid days. The proposed FY 2017 uncompensated care payment methodology is discussed in more detail in section IV.F. of the preamble of this proposed rule.

To estimate the impact of the combined effect of reductions in the percent of individuals under age 65 who are uninsured and additional statutory adjustments (Factor 2) and changes in Medicaid and SSI patient days (components of Factor 3) on the calculation of Medicare DSH payments, including both empirically justified Medicare DSH payments and uncompensated care payments, we compared total DSH payments estimated in the FY 2016 IPPS/LTCH PPS final rule to total DSH payments estimated in this FY 2017 IPPS/LTCH PPS proposed rule. For FY 2016, for each hospital, we calculated the sum of: (1) 25 percent of the estimated amount of what would have been paid as Medicare DSH in FY 2016 in the absence of section 3133 of the Affordable Care Act; and (2) 75 percent of the estimated amount of what would have been paid as Medicare DSH payments in the absence of section 3133 of the Affordable Care Act, adjusted by a Factor 2 of 63.69 percent and multiplied by a Factor 3 as stated in the FY 2016 IPPS/LTCH PPS final rule. For FY 2017, we would calculate the sum of: (1) 25 percent of the estimated amount of what would be paid as Medicare DSH payments in FY 2017 absent section 3133 of Affordable Care Act; and (2) 75 percent of the estimated amount of what would have been paid as Medicare DSH payments absent section 3133 of the Affordable Care Act, adjusted by a Factor 2 of 56.74 percent and multiplied by a Factor 3 as previously stated.

Our analysis included 2,434 hospitals that are projected to be eligible for DSH in FY 2017. It did not include hospitals that terminated their participation from the Medicare program as of July 1, 2015, Maryland hospitals, and SCHs that are expected to be paid based on their hospital-specific rates. In addition, low-income insured days from merged or acquired hospitals were combined into the surviving hospital's CCN, and the nonsurviving CCN was excluded from the analysis. In contrast to FY 2016, hospitals participating in the Rural Community Hospital Demonstration program, which is scheduled to end in FY 2017, are included in the analysis if projected to be eligible for DSH payments during FY 2017. The estimated impact of the proposed changes in Factors 1, 2, and 3 across all hospitals projected to be eligible for DSH payments in FY 2017, by hospital characteristic, is presented in the following table.

MODELED DISPROPORTIONATE SHARE HOSPITAL PAYMENTS FOR ESTIMATED FY 2017 DSHS BY HOSPITAL TYPE: MODEL DSH $ (IN MILLIONS) FROM FY 2016 TO FY 2017

	Number of estimated DSHs (FY 2017) (1)	FY 2016 final rule estimated DSH $* (in millions) (2)	FY 2017 proposed rule estimated DSH $* (in millions) (3)	Dollar difference: FY 2017–FY 2016 (in millions) (4)	Percent change** (5)
Total	2,434	$9,732	$9,598	−$134	−1.4%
By Geographic Location:					
Urban Hospitals	1,927	9,262	9,148	−114	−1.2

MODELED DISPROPORTIONATE SHARE HOSPITAL PAYMENTS FOR ESTIMATED FY 2017 DSHS BY HOSPITAL TYPE: MODEL DSH $ (IN MILLIONS) FROM FY 2016 TO FY 2017—Continued

	Number of estimated DSHs (FY 2017) (1)	FY 2016 final rule estimated DSH $ * (in millions) (2)	FY 2017 proposed rule estimated DSH $ * (in millions) (3)	Dollar difference: FY 2017–FY 2016 (in millions) (4)	Percent change ** (5)
Large Urban Areas	1,048	5,861	5,789	−72	−1.2
Other Urban Areas	879	3,401	3,359	−42	−1.2
Rural Hospitals	507	470	450	−20	−4.3
Bed Size (Urban):					
0 to 99 Beds	337	184	186	2	0.9
100 to 249 Beds	841	2,199	2,171	−28	−1.3
250 to 499 Beds	749	$6,879	$6,791	−$88	−1.3
Bed Size (Rural):					
0 to 99 Beds	375	205	192	−$13	−6.3
100 to 249 Beds	118	209	202	−7	−3.4
250 to 499 Beds	14	56	56	0	−0.3
Urban by Region:					
East North Central	317	1,268	1,253	−$15	−1.2
East South Central	132	575	566	−9	−1.6
Middle Atlantic	233	1,607	1,583	−24	−1.5
Mountain	122	447	449	2	0.4
New England	90	386	388	2	0.5
Pacific	313	1,459	1,453	−6	−0.4
Puerto Rico	42	100	113	12	12.2
South Atlantic	320	1,772	1,737	−35	−2.0
West North Central	103	450	440	−10	−2.3
West South Central	255	1,198	1,168	−30	−2.5
Rural by Region:					
East North Central	65	48	45	−3	−6.7
East South Central	142	151	142	−9	−6.0
Middle Atlantic	26	34	32	−2	−6.2
Mountain	21	16	16	0	0.1
New England	11	15	16	1	8.8
Pacific	7	8	7	−1	−16.2
South Atlantic	88	96	96	0	0.2
West North Central	34	20	19	−1	−5.4
West South Central	113	83	78	−5	−5.9
By Payment Classification:					
Urban Hospitals	1,896	9,212	9,097	−115	−1.2
Large Urban Areas	1,046	5,859	5,788	−72	−1.2
Other Urban Areas	850	3,353	3,310	−43	−1.3
Rural Hospitals	538	520	501	−20	−3.8
Teaching Status:					
Nonteaching	1,551	3,101	3,065	−36	−1.2
Fewer than 100 residents	644	3,206	3,157	−49	−1.5
100 or more residents	239	3,425	3,375	−50	−1.5
Type of Ownership:					
Voluntary	1,400	6,020	5,939	−81	−1.3
Proprietary	550	1,664	1,638	−26	−1.5
Government	482	2,022	1,996	−26	−1.3
Unknown	2	27	25	−2	−5.8
Medicare Utilization Percent:					
0–25	430	3,008	2,972	−36	−1.2
25–50	1,625	6,329	6,235	−94	−1.5
50–65	320	382	379	−3	−0.8
Over 65	59	14	12	−2	−12.9

Source: Dobson | DaVanzo analysis of 2011–2013 Hospital Cost Reports.

* Dollar DSH calculated by [0.25 * estimated section 1886(d)(5)(F) payments] + [0.75 * estimated section 1886(d)(5)(F) payments * Factor 2 * Factor 3]. When summed across all hospitals projected to receive DSH payments, DSH payments are estimated to be $9,372 million in FY 2016 and $9,598 million in FY 2017.

** Percentage change is determined as the difference between Medicare DSH payments modeled for the FY 2017 IPPS/LTCH PPS proposed rule (column 3) and Medicare DSH payments modeled for the FY 2016 IPPS/LTCH final rule (column 2) divided by Medicare DSH payments modeled for the FY 2016 final rule (column 2) 1 times 100 percent.

Changes in projected FY 2017 DSH payments from DSH payments in FY 2016 are primarily driven by three factors: (1) An increase in Factor 1 from $13.411 billion to $14.227 billion; (2) a reduction in the percent of uninsured (Factor 2) from 63.69 percent to 56.74 percent; and (3) a revised proxy methodology for calculating Factor 3 values. The proposed impact analysis found that, across all projected DSH eligible hospitals, FY 2017 DSH payments are estimated at approximately $9.598 billion, or a decrease of approximately 1.4 percent from FY 2016 DSH payments (approximately $9.732 billion). Although Factor 1 increased by approximately 6.1 percent, the reduction in Factor 2 offsets this and results in a net decrease in the amount available to be distributed in uncompensated care payments.

As seen in the above table, percent reductions greater than 1.4 percent indicate that hospitals within the specified category are projected to experience a greater reduction in DSH payments, on average, compared to the universe of FY 2017 projected DSH hospitals. Conversely, percent reductions that are less than 1.4 percent indicate a hospital type is projected to have a smaller reduction than the overall average. The variation in the distribution of payments by hospital characteristic is largely dependent on the change in a given hospital's number of Medicaid days and SSI days used in the Factor 3 computation.

Rural hospitals, grouped by geographic location, payment classification, and bed size, are projected to experience a larger reduction in DSH payments than urban hospitals. Overall, urban hospitals are projected to receive a 1.2 percent decrease in DSH payments, and rural hospitals are projected to receive a 4.3 percent decrease in DSH payments. The smaller the rural hospital, the larger the projected reduction in DSH payments, with rural hospitals that have 0–99 beds projected to experience a 6.3 percent payment reduction, and larger rural hospitals with 250–499 beds projected to experience a 0.3 percent payment reduction. In contrast, the smallest urban hospitals (0–99 beds) are projected to receive an increase in DSH payments of 0.9 percent. Larger hospitals (100–250 beds and 250+ beds) are projected to receive reductions of 1.3 percent in DSH payments that are smaller than the overall average.

By region, projected DSH payment reductions for urban hospitals were largest in the West South Central, West North Central, and South Atlantic regions. The Mountain, New England, and Puerto Rico region hospitals are projected to receive an increase in DSH payments. Reductions in remaining urban hospital regions are generally consistent with the overall average percent reduction of 1.4. Regionally, rural hospitals are projected to receive a wider range of reductions. Rural hospitals in the South Atlantic, Mountain, and most notably New England regions are projected to receive an increase in DSH payments. Reductions are projected to be larger than the overall average in most remaining regions, particularly in the Pacific region.

Teaching hospitals are projected to receive relatively larger reductions than nonteaching hospitals. Voluntary, proprietary, and government hospitals are projected to receive payment reductions generally consistent with the overall average percent reduction of 1.4. Government hospitals are projected to receive slightly smaller reductions in DSH payments, while proprietary hospitals are projected to receive slightly larger reductions than the overall average. Hospitals with over 65 percent Medicare utilization are projected to receive a significant reduction in DSH payments, while lower Medicare utilization percentiles show smaller reductions.

Puerto Rico hospitals are projected to receive an increase in overall DSH payments, including both empirically justified DSH payments and uncompensated care payments, due to the proposal to create proxy values for SSI days for hospitals in Puerto Rico for purposes of calculating Factor 3 of the uncompensated care payment methodology. For FY 2017, Puerto Rico hospitals are projected to receive $113 million in overall DSH and uncompensated care payments, or a 12.2 percent increase from FY 2016 payments ($100 million). Of the estimated $113 million for FY 2017, we estimate that $75 million will be uncompensated care payments to Puerto Rico hospitals. This represents an increase of approximately 11.2 percent, or $7.6 million, in FY 2017 compared to the estimated $68 million in uncompensated care payments to Puerto Rico hospitals in FY 2016. Moreover, we estimate that uncompensated care payments to Puerto Rico hospitals for FY 2017 are 12.6 percent, or $8.4 million, higher with the proposed SSI proxy than they otherwise would have been without the proposed SSI proxy for FY 2017. In other words, without the proposed SSI proxy, we would have expected uncompensated care payments to Puerto Rico hospitals to decline by approximately $0.9 million between FY 2016 and FY 2017. We note that because the proposed SSI proxy for Puerto Rico hospitals increases the number of days in the denominator of Factor 3, this affects hospitals nationally. We estimate that uncompensated care payments to non-Puerto Rico hospitals for FY 2017 are approximately 0.1 percent lower with the proposed SSI proxy than they otherwise would have been without the proposed SSI proxy.

3. Effects of Proposed Reduction Under the Hospital Readmissions Reduction Program

In section IV.G. of the preamble of this proposed rule, we discuss our proposals for the FY 2017 Hospital Readmissions Reduction Program (established under section 3025 of the Affordable Care Act), which requires a reduction to a hospital's base operating DRG payments to account for excess readmissions. For FY 2017, the reduction is based on a hospital's risk-adjusted readmission rate during a 3-year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG). This provision is not budget neutral. A hospital's readmission adjustment is the higher of a ratio of the hospital's aggregate payments for excess readmissions to their aggregate payments for all discharges, or a floor, which has been defined in the statute as 0.97 (or a 3.0 percent reduction). A hospital's base operating DRG payment (that is, wage-adjusted DRG payment amount, as discussed in section IV.G. of the preamble of this proposed rule) is the portion of the IPPS payment subject to the readmissions payment adjustment (DSH, IME, outliers and low-volume add-on payments are not subject to the readmissions adjustment). In this proposed rule, we estimate that 2,603 hospitals would have their base operating DRG payments reduced by their proxy FY 2017 hospital-specific readmissions adjustment. As a result, we estimate that the Hospital Readmissions Reduction Program would save approximately $523 million in FY 2017, an increase of $100 million over the estimated FY 2016 savings.

4. Effects of Proposed Changes Under the FY 2017 Hospital Value-Based Purchasing (VBP) Program

In section IV.H. of the preamble of this proposed rule, we discuss the Hospital VBP Program under which the Secretary makes value-based incentive payments to hospitals based on their performance on measures during the performance period with respect to a fiscal year. These incentive payments will be funded for FY 2017 through a reduction to the FY 2017 base operating DRG payment amount for the discharge for the hospital for such fiscal year, as required by section 1886(o)(7)(B) of the Act. The applicable percentage for FY 2017 and subsequent years is 2 percent. The total amount available for value-based incentive payments must be equal to the total amount of reduced payments for all hospitals for the fiscal year, as estimated by the Secretary.

In section IV.H. of the preamble of this proposed rule, we estimate the available pool of funds for value-based incentive payments in the FY 2017 program year, which, in accordance with section 1886(o)(7)(C)(v) of the Act, will be 2.00 percent of base operating DRG payments, or a total of approximately $1.7 billion. This estimated available pool for FY 2017 is based on the historical pool of hospitals that were eligible to participate in the FY 2016 program year and the payment information from the December 2015 update to the FY 2015 MedPAR file.

The proposed estimated impacts of the FY 2017 program year by hospital characteristic, found in the table below, are based on historical TPSs. We used the FY 2016 program year's TPSs to calculate the proxy adjustment factors used for this impact analysis. These are the most recently available scores that hospitals were given an opportunity to review and correct. The proxy adjustment factors use estimated annual base operating DRG payment amounts derived from the December 2015 update to the FY 2015 MedPAR file. The proxy adjustment factors can be found in Table 16 associated with this proposed rule (available via the Internet on the CMS Web site).

The impact analysis shows that, for the FY 2017 program year, the number of hospitals that would receive an increase in their base operating DRG payment amount is higher than the number of hospitals that would receive a decrease. Among urban hospitals, those in the New England, South Atlantic, East North Central, East South Central, West North Central, West South Central, Mountain, and Pacific regions would have an increase, on average, in their base operating DRG payment amount. Urban hospitals in the Middle Atlantic region would receive an average decrease in their base operating DRG payment amount. Among rural hospitals, those in all regions would have an increase, on average, in their base operating DRG payment amounts.

On average, hospitals that receive a higher (50–65) percent of DSH payments would receive decreases in base operating DRG payment amount. With respect to hospitals' Medicare utilization as a percent of inpatient days (MCR), those hospitals with an MCR above 65 percent would have the largest average increase in base operating DRG payment amount.

Nonteaching hospitals would have an average increase, and teaching hospitals would experience an average decrease in base operating DRG payment amount.

IMPACT ANALYSIS OF BASE OPERATING DRG PAYMENT AMOUNT PROPOSED CHANGES RESULTING FROM THE FY 2017 HOSPITAL VBP PROGRAM

	Number of hospitals	Average (%)
By Geographic Location:		
All Hospitals	3,041	0.244
Large Urban	1,247	0.117
Other Urban	1,046	0.202
Rural Area	748	0.514
Urban hospitals	2,293	0.156
0–99 beds	517	0.708
100–199 beds	719	0.143
200–299 beds	430	−0.035
300–499 beds	419	−0.146
500 or more beds	208	−0.171
Rural hospitals	748	0.514
0–49 beds	265	0.695
50–99 beds	286	0.540
100–149 beds	115	0.304
150–199 beds	45	0.159
200 or more beds	37	0.103
By Region:		
Urban By Region	2,293	0.156
New England	110	0.152
Middle Atlantic	297	−0.065
South Atlantic	389	0.108
East North Central	368	0.204
East South Central	141	0.126
West North Central	155	0.370
West South Central	324	0.211
Mountain	159	0.128
Pacific	350	0.225
Rural By Region	748	0.514
New England	20	0.528
Middle Atlantic	53	0.373
South Atlantic	117	0.621
East North Central	112	0.514
East South Central	138	0.389
West North Central	94	0.623
West South Central	135	0.416
Mountain	55	0.713
Pacific	24	0.677
By MCR Percent:		
0–25	374	0.131
25–50	2,024	0.205
50–65	508	0.409
Over 65	126	0.539
Missing	9	0.204
BY DSH Percent:		
0–25	1,427	0.384
25–50	1,320	0.154
50–65	156	−0.067
Over 65	138	0.007
By Teaching Status:		
Non-Teaching	2,041	0.381
Teaching	1,000	−0.036

Actual FY 2017 program year's TPSs will not be reviewed and corrected by hospitals until after the FY 2017 IPPS/LTCH PPS final rule has been published. Therefore, the same historical universe of eligible hospitals and corresponding TPSs from the FY 2016 program year will be used for the updated impact analysis in that final rule.

5. Effects of Proposed Changes to the HAC Reduction Program for FY 2017

In section IV.I. of the preamble of this proposed rule, we discuss the proposed changes to the HAC Reduction Program for FY 2017. The table and analysis below show the estimated cumulative effect of the measures and scoring system for the HAC Reduction Program proposed in this proposed rule. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49575 through 49576), we finalized a Total HAC Score methodology that assigns, for FY 2017, weights for Domain 1 and Domain 2 at 15 percent and 85 percent, respectively. Based on this methodology, the table below presents data on the estimated proportion of hospitals in the worst-performing quartile of the Total HAC Scores by hospital characteristic. We note that because scores will undergo a 30-day review and correction period by the hospitals that will not conclude until after the publication of the FY 2017 IPPS/LTCH PPS final rule, we are not providing hospital-level data or a hospital-level payment impact in conjunction with this FY 2017 IPPS/LTCH PPS proposed rule.

To estimate the impact of the FY 2017 HAC Reduction Program, we used, as previously finalized, AHRQ PSI 90 measure results based on Medicare FFS discharges from July 2013 through June 2015 and version 5.0.1 (recalibrated) of the AHRQ software. For the CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI measure results, we used standardized infection ratios (SIRs) calculated with hospital surveillance data reported to the NHSN for infections occurring between January 1, 2013 and December 31, 2014.

To analyze the results by hospital characteristic, we used the FY 2016 Final Rule Impact File. This table includes 3,225 non-Maryland hospitals that had a Total HAC Score for FY 2017. Of these, 3,211 hospitals had information for geographic location, region, bed size, DSH percent, and teaching status, 3,197 had information for ownership, and 3,191 had information for MCR percent. Maryland hospitals and hospitals without a Total HAC Score are not included in the table below.

ESTIMATED PROPORTION OF HOSPITALS IN THE WORST-PERFORMING QUARTILE (75TH PERCENTILE) OF THE TOTAL HAC SCORE FOR THE FY 2017 HAC REDUCTION PROGRAM

[By hospital characteristic]

Hospital characteristic	Number of hospitals[a]	Number of hospitals in the worst-performing quartile[b]	Percent of hospitals in the worst-performing quartile[c]
Total[d]	3,225	774	24.0
By Geographic Location:			
All hospitals:			
Urban	2,403	656	27.3
Rural	808	108	13.4
Urban hospitals:			
1–99 beds	593	90	15.2
100–199 beds	737	164	22.3
200–299 beds	436	128	29.4
300–399 beds	273	103	37.7
400–499	151	62	41.1
500 or more beds	213	109	51.2
Rural hospitals:			
1–49 beds	306	44	14.4
50–99 beds	294	32	10.9
100–149 beds	120	11	9.2
150–199 beds	47	11	23.4
200 or more beds	41	10	24.4
By Region:			
New England	134	46	34.3
Mid-Atlantic	367	130	35.4
South Atlantic	520	131	25.2
East North Central	499	105	21.0
East South Central	299	58	19.4
West North Central	262	39	14.9
West South Central	510	79	15.5
Mountain	225	64	28.4
Pacific	395	112	28.4
By DSH Percent:[e]			
0–24	1,512	336	22.2
25–49	1,370	329	24.0
50–64	170	48	28.2
65 and over	159	51	32.1
By Teaching Status:[f]			
Non-teaching	2,189	398	18.2
Fewer than 100 residents	1,022	366	35.8
100 or more residents	777	230	29.6
By Type of Ownership:			
Voluntary	1,874	480	25.6
Proprietary	834	160	19.2
Government	489	122	24.9
By MCR Percent:			
0–24	480	143	29.8
25–49	2,096	498	23.8
50–64	533	104	19.5
65 and over	82	14	17.1

Source: FY 2017 HAC Reduction Program Proposed Rule Preliminary Results. Scores are based on AHRQ PSI 90 data from July 2013 through June 2015 and CDC CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia and CDI data from January 2013 to December 2014. Hospital Characteristics are based on the FY 2016 Final Rule Impact File updated on October 8, 2015.

[a] The total number of non-Maryland hospitals with a Total HAC Score with hospital characteristic data (3,211 for geographic location, region, bed size, DSH percent, and teaching status; 3,197 for type of ownership; and 3,191 for MCR) does not add up to the total number of non-Maryland hospitals with a Total HAC Score for the FY 2017 HAC Reduction Program (3,225) because 14 hospitals are not included in the FY 2016 Final Rule Impact File and not all hospitals have data for all characteristics.

[b] This column is the number of non-Maryland hospitals with a Total HAC Score within the corresponding characteristic that are estimated to be in the worst-performing quartile.

[c] This column is the percent of hospitals within each characteristic that are estimated to be in the worst-performing quartile. The percentages are calculated by dividing the number of non-Maryland hospitals with a Total HAC Score in the worst-performing quartile by the total number of non-Maryland hospitals with a Total HAC Score within that characteristic.

[d] Total excludes 47 Maryland hospitals and 64 non-Maryland hospitals without a Total HAC Score for FY 2017.

[e] A hospital is considered to be a DSH hospital if it has a disproportionate patient percentage (DPP) greater than zero.

[f] A hospital is considered to be a teaching hospital if it has an IME adjustment factor for Operation PPS (TCHOP) greater than zero.

6. Effects of Proposed Policy Changes Relating to Direct GME and IME Payments for Rural Training Tracks at Urban Hospitals

In section IV.J. of the preamble of this proposed rule, we discuss our proposal to extend the period for establishing rural track FTE limitations from 3 years to 5 years for purposes of direct GME and IME payments to urban hospitals with rural track training programs. Specifically, we are proposing to revise the regulations to permit that, in the first 5 program years (rather than the first 3 program years) of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents training in the rural training track at the urban hospital, and beginning with the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural training track's existence, the rural track FTE limitation would take effect. This proposed change addresses concerns expressed by the hospital community that rural training tracks, like any program, should have a sufficient amount of time for a hospital to "grow" and to establish a rural track FTE limitation that reflects the number of FTE residents that it will actually train, once the program is fully grown. In section IV.J. of the preamble of this proposed rule, we explain that because we inadvertently did not also amend the separate direct GME and IME regulations regarding the growth window and effective date of FTE limitations for rural track training programs when we amended the regulations regarding the 5-year growth window in the FY 2013 IPPS/LTCH PPS final rule and regarding the additional changes we made in the FY 2015 IPPS/LTCH PPS final rule, we are proposing that the effective date regarding the change in the growth window also be effective for rural track training programs started on or after October 1, 2012. Mostly due to the relatively small size of rural track programs, we estimate that the proposal would cost approximately $1 million by the end of the 10-year period, a negligible cost.

7. Effects of Implementation of Rural Community Hospital Demonstration Program

In section IV.K. of the preamble of this proposed rule, for FY 2017, we discuss our implementation of section 410A of Public Law 108–173, as amended, which requires the Secretary to conduct a demonstration that would modify payments for inpatient services for up to 30 rural community hospitals. Section 410A(c)(2) requires that in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented.

As discussed in section IV.K. of the preamble of this proposed rule, in the IPPS final rules for each of the previous 12 fiscal years, we have estimated the additional payments made by the program for each of the participating hospitals as a result of the demonstration. In order to achieve budget neutrality, we have adjusted the national IPPS rates by an amount sufficient to account for the added costs of this demonstration. In other words, we have applied budget neutrality across the payment system as a whole rather than across the participants of this demonstration. The language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration was not implemented but does not identify the range across which aggregate payments must be held equal.

In this FY 2017 proposed rule, we are proposing a different methodology as compared to previous years for analyzing the costs attributable to the demonstration for FY 2017. The demonstration will have substantially phased out by the beginning of FY 2017. The 7 "originally participating hospitals", that is, those hospitals that were selected for the demonstration in 2004 and 2008, ended their participation in the 5-year extension period authorized by the Affordable Care Act prior to the start of FY 2016. In addition, the participation period for the 14 hospitals that entered the demonstration following the extension of the demonstration mandated by the Affordable Care Act and that are still participating will end on a rolling basis according to the end dates of the hospitals' cost report periods, respectively, from April 30, 2016 through December 31, 2016. Of these 14 hospitals, 10 hospitals will end participation on or before September 30, 2016, leaving 4 hospitals participating for the last 3 months of CY 2016 (that is, the first 3 months of FY 2017). Given the small number of participating hospitals and the limited time of participation, we are proposing to forego the process of estimating the costs attributable to the demonstration for FY 2017 and to instead analyze the set of finalized cost reports for reporting periods beginning in FY 2016 when they become available.

In previous IPPS/LTCH PPS final rules, we have determined the amount by which the actual costs of the demonstration for an earlier, previous year differed from the estimated costs of the demonstration set forth in the corresponding final rule for the corresponding fiscal year, and we incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. We note that we have calculated this difference between the actual costs of the demonstration for FYs 2005 through 2010, as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years. In this proposed rule, we are proposing to conduct this analysis for FYs 2011 through 2016 at one time, when all of the finalized cost reports for cost reporting periods beginning in FYs 2011 through 2016 are available. Given the general lag of 3 years in finalizing cost reports, we expect any such analysis to be conducted in FY 2020.

Because, as discussed earlier, we are proposing that we would not calculate and apply an estimated budget neutrality offset amount for FY 2017, but instead analyze the set of finalized cost reports for cost reporting periods beginning in FY 2016 when they become available, and are proposing to reconcile the budget neutrality offset amounts for FYs 2011 through 2016 with the actual costs of the demonstration once the finalized cost reports for all of these years are available, we believe there would be no impact from the demonstration on the national IPPS rates for FY 2017.

8. Effects of Proposed Implementation of the Notice of Observation Treatment and Implications for Care Eligibility Act (NOTICE Act)

In section IV.L. of the preamble of this proposed rule, we discuss our proposal to implement section 1866(a)(1)(Y) of the Act as amended by the NOTICE Act (Pub. L. 114–42) by revising the basic commitments providers agree to as part of participating in Medicare under a provider agreement by establishing regulations that would specify a process for hospitals and CAHs to notify an individual, orally and in writing, regarding the individual's receipt of observation services as an outpatient for more than 24 hours and the implications of receiving such services. The statute mandates the Secretary develop a plain language written notice for this purpose. The written notice must be delivered no later than 36 hours after observation services are initiated. We have developed a standardized format for the notice, which is undergoing OMB approval. The notice would be disseminated during the normal course of related business activities. In 2014, there were approximately 977,000 claims for Medicare outpatient observation services lasting greater than 24 hours furnished by 6,142 hospitals and CAHs.[322] We refer readers to section IX.B. of the preamble of this proposed rule for a discussion of the burden associated with this notice requirement.

9. Effects of Proposed Technical Changes and Correction of Typographical Errors in Certain Regulations Under 42 CFR Part 413 Relating to Costs to Related Organizations and Medicare Cost Reports

In section IV.M. of the preamble of this proposed rule, we discuss a number of proposed technical changes or corrections of typographical errors in 42 CFR part 413 relating to costs to related organizations and Medicare cost reports that need to be made. We believe that the impact of these proposed technical changes and corrections is negligible.

10. Effects of Proposed Implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration

In section VI.B. of the preamble of this proposed rule, we discuss the implementation of the FCHIP demonstration, which will allow eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care, and other health care services to Medicare beneficiaries in no more than four

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[322] Source: CMS Office of Enterprise and Data Analytics.

States. CMS has selected CAHs to participate in the demonstration, and budget neutrality estimates will be based on the demonstration period, which is expected to be August 1, 2016 through July 31, 2019. The selected CAHs are located in three States: Montana, Nevada, and North Dakota. The demonstration design includes three intervention prongs, under which specific waivers of Medicare payment rules will allow for enhanced payment: telemedicine, nursing facility, and ambulance services. These waivers were formulated with the goal of increasing access to care with no net increase in costs.

We have specified the payment enhancements for the demonstration, and based our selection of CAHs for participation, with the goal of maintaining the budget neutrality of the demonstration on its own terms (that is, the demonstration will produce savings from reduced transfers and admissions to other health care providers, thus offsetting any increase in payments resulting from the demonstration). However, because of the small size of this demonstration program and uncertainty associated with projected Medicare utilization and costs, we are proposing a contingency plan to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met. Accordingly, if analysis of claims data for the Medicare beneficiaries receiving services at each of the participating CAHs, as well as of other data sources, including cost reports for these CAHs, shows that increases in Medicare payments under the demonstration during the 3-year period are not sufficiently offset by reductions elsewhere, we will recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide. The demonstration is projected to impact payments to participating CAHs under both Medicare Part A and Part B. Thus, in the event that we determine that aggregate payments under the demonstration exceed the payments that would otherwise have been made, we are proposing that CMS would recoup payments through reductions of Medicare payments to all CAHs under both Medicare Part A and Part B. Because of the small scale of the demonstration, it would be not be feasible to implement budget neutrality by reducing only payments to the participating CAH providers. We are proposing to make the reduction to payments to all CAHs, not just those participating in the demonstration, because the FCHIP program is specifically designed to test innovations that affect delivery of services by this provider category. We believe that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of the Act permits the agency to implement the budget neutrality provision in this manner. The statutory language refers merely to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented, and does not identify the range across which aggregate payments must be held equal.

Given the 3-year period of performance of the FCHIP demonstration and the time needed to conduct the budget neutrality analysis, we are proposing that, in the event the demonstration is found not to have been budget neutral, any excess costs would be recouped over a period of three cost report periods, beginning in CY 2020. Therefore, this proposal does not impact any national payment system for FY 2017.

I. Effects of Proposed Changes in the Capital IPPS

1. General Considerations

For the impact analysis presented below, we used data from the December 2015 update of the FY 2015 MedPAR file and the December 2015 update of the Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the proposed changes to the capital prospective payment system do not incorporate cost data, we used the December 2015 update of the most recently available hospital cost report data (FYs 2013 and 2014) to categorize hospitals. Our analysis has several qualifications. We use the best data available and make assumptions about case-mix and beneficiary enrollment as described later in this section.

Due to the interdependent nature of the IPPS, it is very difficult to precisely quantify the impact associated with each change. In addition, we draw upon various sources for the data used to categorize hospitals in the tables. In some cases (for instance, the number of beds), there is a fair degree of variation in the data from different sources. We have attempted to construct these variables with the best available sources overall. However, it is possible that some individual hospitals are placed in the wrong category.

Using cases from the December 2015 update of the FY 2015 MedPAR file, we simulated payments under the capital IPPS for FY 2016 and FY 2017 for a comparison of total payments per case. Any short-term, acute care hospitals not paid under the general IPPS (for example, Indian Health Service hospitals and hospitals in Maryland) are excluded from the simulations.

The methodology for determining a capital IPPS payment is set forth at § 412.312. The basic methodology for calculating the proposed capital IPPS payments in FY 2017 is as follows:

(Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME adjustment factor, if applicable).

In addition to the other adjustments, hospitals may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. We modeled payments for each hospital by multiplying the capital Federal rate by the GAF and the hospital's case-mix. We then added estimated payments for indirect medical education, disproportionate share, and outliers, if applicable. For purposes of this impact analysis, the model includes the following assumptions:

- We estimate that the Medicare case-mix index will increase by 0.5 percent in both FYs 2016 and 2017.
- We estimate that Medicare discharges will be approximately 11.3 million in FY 2016 and 11.5 million in FY 2017.
- The capital Federal rate was updated beginning in FY 1996 by an analytical framework that considers changes in the prices associated with capital-related costs and adjustments to account for forecast error, changes in the case-mix index, allowable changes in intensity, and other factors. As discussed in section III.A.1.a. of the Addendum to this proposed rule, the proposed update is 0.9 percent for FY 2017.
- In addition to the proposed FY 2017 update factor, the proposed FY 2017 capital Federal rate was calculated based on a proposed GAF/DRG budget neutrality adjustment factor of 0.9993, a proposed outlier adjustment factor of 0.9374, and a proposed adjustment of (1/0.998) to permanently remove the 0.2 percent adjustment, as well as a proposed temporary 2-midnight adjustment of 1.006. The 2-midnight adjustments are discussed in section V.C. of the preamble of this proposed rule and are consistent with the proposed 2-midnight adjustments on the operating Federal rate. As discussed in section V.C. of the preamble of this proposed rule, we are not proposing to make an additional MS–DRG documentation and coding adjustment to the capital IPPS Federal rates for FY 2017.

2. Results

We used the actuarial model previously described in section I.I. of Appendix A of this proposed rule to estimate the potential impact of our proposed changes for FY 2017 on total capital payments per case, using a universe of 3,330 hospitals. As previously described, the individual hospital payment parameters are taken from the best available data, including the December 2015 update of the FY 2015 MedPAR file, the December 2015 update to the PSF, and the most recent cost report data from the December 2015 update of HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2016 and estimated total payments per case for FY 2017 based on the proposed FY 2017 payment policies. Column 2 shows estimates of payments per case under our model for FY 2016. Column 3 shows estimates of payments per case under our model for FY 2017. Column 4 shows the total percentage change in payments from FY 2016 to FY 2017. The change represented in Column 4 includes the proposed 0.9 percent update to the capital Federal rate and other proposed changes in the adjustments to the capital Federal rate. The comparisons are provided by: (1) Geographic location; (2) region; and (3) payment classification.

The simulation results show that, on average, proposed capital payments per case in FY 2017 are expected to increase as compared to capital payments per case in FY 2016. This expected increase is due to the proposed approximately 1.7 percent increase in the capital Federal rate for FY 2017 as compared to the FY 2016 capital Federal rate and, to a lesser degree, changes to the MS–DRG reclassifications and recalibrations. (For a discussion of the determination of the capital Federal rate, we refer readers to section III.A. of the Addendum to this proposed rule.) The proposed increase in capital payments per case due to the effects of changes to the MS–DRG reclassifications and recalibrations is expected to be slightly greater for urban hospitals than for rural hospitals. However, less than half of the hospitals in urban areas are expected to experience a slight increase in capital payments per case due to the effects of proposed changes to the GAFs, while the remainder of these urban area hospitals would experience no change or a decrease in capital payments per case due to proposed changes in the GAFs. For most hospitals in rural areas, proposed changes in the GAFs are expected to increase capital payments, to a greater or lesser extent, except for two rural areas where proposed changes in the GAFs are expected to decrease capital payments per case. These regional effects of the proposed changes to the GAFs on capital payments are consistent with the projected changes in payments due to proposed changes in the wage index (and proposed policies affecting the wage index) as shown in Table I in section I.G. of this Appendix A.

The net impact of these proposed changes is an estimated proposed 2.0 percent change in capital payments per case from FY 2016 to FY 2017 for all hospitals (as shown in Table III).

The geographic comparison shows that, on average, hospitals in all classifications (urban and rural) would experience an increase in capital IPPS payments per case in FY 2017 as compared to FY 2016. Capital IPPS payments per case for hospitals in "large urban areas" have an estimated increase of 2.0 percent, while hospitals in rural areas, on average, are expected to experience a 2.1 percent increase in proposed capital payments per case from FY 2016 to FY 2017. Capital IPPS payments per case for "other urban hospitals" are also estimated to increase 2.1 percent. The primary factor contributing to the difference in the proposed projected increase in capital IPPS payments per case for urban hospitals as compared to rural hospitals is the proposed changes to the MS–DRGs reclassifications and recalibrations.

The comparisons by region show that the estimated increases in capital payments per case from FY 2016 to FY 2017 in urban areas range from a 2.7 percent increase for the West South Central urban region to a 0.7 percent increase for the New England urban region. For rural regions, the Middle Atlantic rural region is projected to experience the largest increase in capital IPPS payments per case of 2.9 percent; the Mountain rural region is projected to experience the smallest increase in capital IPPS payments per case of 0.7 percent. The proposed change in the GAFs is the main factor for the Mountain rural region experiencing the smallest projected increase in capital IPPS payments among rural regions, and it is also the main contributor for the smallest projected increase in capital IPPS payments for the New England urban region.

Hospitals of all types of ownership (that is, voluntary hospitals, government hospitals, and proprietary hospitals) are expected to experience an increase in capital payments per case from FY 2016 to FY 2017. The proposed increase in capital payments for voluntary and proprietary hospitals is estimated to be 2.0 percent and 2.2 percent, respectively. For government hospitals, the increase is estimated to be 1.8 percent.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2017. Reclassification for wage index purposes also affects the GAFs because that factor is constructed from the hospital wage index. To present the effects of the hospitals being reclassified as of the publication of this proposed rule for FY 2017, we show the average capital payments per case for reclassified hospitals for FY 2017. Urban reclassified hospitals are expected to experience an increase in capital payments of 2.0 percent; urban nonreclassified hospitals are expected to experience an increase in capital payments of 2.1 percent. The estimated percentage increase for rural reclassified hospitals is 2.3 percent, and for rural nonreclassified hospitals, the estimated percentage increase is 1.5 percent. Other reclassified hospitals (section 1886(d)(8)(B) of the Act) are expected to experience the largest increase in capital payments of 2.6 percent.

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE

[FY 2016 payments compared to FY 2017 payments]

	Number of hospitals	Average FY 2016 payments/ case	Average FY 2017 payments/ case	Change
By Geographic Location:				
All hospitals	3,330	895	913	2.0
Large urban areas (populations over 1 million)	1,378	991	1,010	2.0
Other urban areas (populations of 1 million of fewer)	1,134	855	873	2.1
Rural areas	818	607	619	2.1
Urban hospitals	2,512	929	948	2.0
0–99 beds	656	752	766	2.0
100–199 beds	765	805	819	1.8
200–299 beds	449	848	864	1.9
300–499 beds	429	943	963	2.1
500 or more beds	213	1,118	1,142	2.1
Rural hospitals	818	607	619	2.1
0–49 beds	320	509	519	2.0
50–99 beds	292	568	579	2.1
100–149 beds	119	599	610	1.8
150–199 beds	46	656	669	2.1
200 or more beds	41	727	744	2.3
By Region:				
Urban by Region	2,512	929	948	2.0
New England	116	1,011	1,018	0.7
Middle Atlantic	315	1,035	1,050	1.5
South Atlantic	406	826	843	2.1
East North Central	390	892	913	2.3
East South Central	147	780	800	2.5
West North Central	163	907	926	2.1
West South Central	384	839	862	2.7
Mountain	163	961	980	1.9
Pacific	377	1,194	1,218	2.0
Puerto Rico	51	426	450	5.5
Rural by Region	818	607	619	2.1
New England	21	847	866	2.3
Middle Atlantic	55	579	595	2.9

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE—Continued

[FY 2016 payments compared to FY 2017 payments]

	Number of hospitals	Average FY 2016 payments/ case	Average FY 2017 payments/ case	Change
South Atlantic	127	573	581	1.5
East North Central	115	627	642	2.4
East South Central	156	552	563	2.0
West North Central	99	655	666	1.8
West South Central	161	524	538	2.6
Mountain	60	710	715	0.7
Pacific	24	794	813	2.4
By Payment Classification:				
All hospitals	3,330	895	913	2.0
Large urban areas (populations over 1 million)	1,372	992	1,011	2.0
Other urban areas (populations of 1 million of fewer)	1,083	860	878	2.1
Rural areas	875	622	634	1.9
Teaching Status:				
Non-teaching	2,275	755	770	1.9
Fewer than 100 Residents	804	868	886	2.1
100 or more Residents	251	1,264	1,290	2.1
Urban DSH:				
100 or more beds	1,608	954	973	2.1
Less than 100 beds	330	688	700	1.8
Rural DSH:				
Sole Community (SCH/EACH)	266	590	603	2.2
Referral Center (RRC/EACH)	347	652	665	2.0
Other Rural:				
100 or more beds	33	537	545	1.4
Less than 100 beds	149	515	523	1.6
Urban teaching and DSH:				
Both teaching and DSH	880	1,029	1,051	2.1
Teaching and no DSH	107	928	942	1.5
No teaching and DSH	1,058	800	816	2.0
No teaching and no DSH	410	804	820	1.9
Rural Hospital Types:				
Non special status hospitals	2,522	931	949	2.0
RRC/EACH	193	754	774	2.6
SCH/EACH	326	689	702	2.0
SCH, RRC and EACH	126	735	749	1.9
Hospitals Reclassified by the Medicare Geographic Classification Review Board:				
FY2017 Reclassifications:				
All Urban Reclassified	576	952	971	2.0
All Urban Non-Reclassified	1,879	925	944	2.1
All Rural Reclassified	277	636	651	2.3
All Rural Non-Reclassified	484	570	578	1.5
Other Reclassified Hospitals (Section 1886(d)(8)(B))	57	582	597	2.6
Type of Ownership:				
Voluntary	1,914	908	927	2.0
Proprietary	858	803	820	2.2
Government	516	946	963	1.8
Medicare Utilization as a Percent of Inpatient Days:				
0–25	517	1,086	1,109	2.2
25–50	2,128	899	917	2.0
50–65	546	730	744	1.9
Over 65	94	518	528	2.0

J. Effects of Proposed Payment Rate Changes and Policy Changes Under the LTCH PPS

1. Introduction and General Considerations

In section VII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule, we set forth the proposed annual update to the payment rates for the LTCH PPS for FY 2017. In the preamble of this proposed rule, we specify the statutory authority for the proposed provisions that are presented, identify those proposed policies, and present rationales for our proposed decisions as well as alternatives that were considered. In this section of Appendix A to this proposed rule, we discuss the impact of the proposed changes to the payment rate, factors, and other payment rate policies related to the LTCH PPS that are presented in the preamble of this proposed rule in terms of their estimated fiscal impact on the Medicare budget and on LTCHs.

There are 420 LTCHs included in this impacts analysis, which includes data for 78 nonprofit (voluntary ownership control) LTCHs, 325 proprietary LTCHs, and 17 LTCHs that are government-owned and operated. (We note that, although there are currently approximately 430 LTCHs, for purposes of this impact analysis, we excluded the data of all-inclusive rate providers consistent with the development of the proposed FY 2017 MS–LTC–DRG relative weights (discussed in section VII.C.3.c. of the preamble of this proposed rule).) In the impact analysis, we used the proposed payment rate, factors, and policies presented in this proposed rule, which includes the continued transition to the site neutral payment rate required by section 1886(m)(6)(A) of the Act (discussed in section VII.B. of the preamble of this proposed rule), the proposed 1.45 percent annual update to the LTCH PPS standard Federal payment rate in accordance with section 1886(m)(5)(C) of the Act (which is based on the full estimated increase of the proposed revised and rebased LTCH PPS market basket and the reductions required by sections 1886(m)(3) and (m)(4) of the Act), the proposed update to the MS–LTC–DRG classifications and relative weights, the proposed update to the wage index values and labor-related share, and the best available claims and CCR data to estimate the proposed change in payments for FY 2017.

Under the dual rate LTCH PPS payment structure, payment for LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) is based on the LTCH PPS standard Federal payment rate. Consistent with the statute, the site neutral payment rate is the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), including any applicable outlier payments as specified in § 412.525(a); or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2). In addition, there are two separate HCO targets—one for LTCH PPS standard Federal payment rate cases and one for site neutral payment rate cases. The statute also establishes a transitional payment method for cases that are paid the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 and FY 2017. The transitional payment amount for site neutral payment rate cases is a blended payment rate, which is calculated as 50 percent of the applicable site neutral payment rate amount for the discharge as determined under new § 412.522(c)(1) and 50 percent of the applicable LTCH PPS standard Federal payment rate for the discharge determined under § 412.523.

Based on the best available data for the 420 LTCHs in our database that were considered in the analyses used for this proposed rule, we estimate that overall LTCH PPS payments in FY 2017 would decrease by approximately 6.9 percent (or approximately $355 million). This projection takes into account estimated payments for LTCH cases in our database that would have met the patient-level criteria and been paid the LTCH PPS standard Federal payment rate if those criteria had been in effect at the time of the discharge, and estimated payments for LTCH cases that would not have met the patient-level criteria and been paid under the site neutral payment rate if that rate had been in effect at the time of the discharge, as described in the following paragraph.

The statutory transitional payment method for cases that are paid the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 or FY 2017 uses a blended payment rate, which is determined as 50 percent of the site neutral payment rate amount for the discharge and 50 percent of the standard Federal prospective payment rate amount for the discharge (§ 412.522(c)(3)). The transitional blended payment rate uses the same blend percentages (that is, 50 percent) for both years of the 2-year transition period. Therefore, when estimating FY 2017 LTCH PPS payments for site neutral payment rate cases for this impact analysis, the transitional blended payment rate was applied to all such cases because all discharges in FY 2017 will either be in the hospital's cost reporting period that began during FY 2016 or in the hospital's cost reporting period that will begin during FY 2017. However, when estimating FY 2016 LTCH PPS payments for site neutral payment rate cases for this impact analysis because the statute specifies that the site neutral payment rate effective date for a given LTCH is determined based on the date on which that LTCH's cost reporting period begins during FY 2016, we included an adjustment to account for this rolling effective date, consistent with the approach used for the LTCH PPS impact analysis presented in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49831). This approach accounts for the fact that LTCHs with discharges in FY 2016 that are in cost reporting periods that begin *before* October 1, 2015, continued to be paid for all discharges (including those that did not meet the patient-level criteria for exclusion from the site neutral payment rate) at the LTCH PPS standard Federal payment rate until the start of their first cost reporting period beginning *after* October 1, 2015.

For purposes of this impact analysis, to estimate total FY 2016 LTCH PPS payments for site neutral payment rate cases, we used the same approach as was used in the FY 2016 IPPS/LTCH PPS final rule. In summary, under this approach, we grouped LTCHs based on the quarter of FY 2016 their cost reporting periods began during FY 2016. For example, LTCHs with cost reporting periods that began during October through December 2015 began during the first quarter of FY 2016. For LTCHs grouped in each quarter of FY 2016, we modeled those LTCHs' estimated FY 2016 site neutral payment rate payments under the transitional blended payment rate based on the quarter in which the LTCHs in each group become subject to the site neutral payment rate. Then, we modeled for LTCHs grouped in each quarter of FY 2016, estimated FY 2016 payments under the LTCH PPS standard Federal payment rate based on the quarter in which the LTCHs in each group become subject to the site neutral payment rate. (For additional details on our method of taking into account the rolling effective date of the application of the site neutral payment rate when estimating payments for FY 2016, we refer readers to the description presented in FY 2016 IPPS/LTCH PPS final rule (80 FR 49831).) We continue to believe that this approach is a reasonable means of taking the rolling effective date into account when estimating FY 2016 payments.

Based on the fiscal year start dates recorded in the December 2015 update of the PSF, of the 420 LTCHs in our database of LTCH claims from the December 2015 update of the FY 2015 MedPAR files used for this proposed rule, the following percentages apply in the approach previously described: 9.9 percent of site neutral payment rate cases are from LTCHs whose cost reporting periods begin in the first quarter of FY 2016; 26.4 percent of site neutral payment rate cases are from LTCHs whose cost reporting periods begin in the second quarter of FY 2016; 10.3 percent of site neutral payment rate cases are from LTCHs whose cost reporting periods begin in the third quarter of FY 2016; and 53.4 percent of site neutral payment rate cases are from LTCHs whose cost reporting periods begin in the fourth quarter of FY 2016.

Based on the FY 2015 LTCH cases that were used for the analyses in this proposed rule, approximately 45 percent of those LTCH cases would have been classified as site neutral payment rate cases if the site neutral payment rate had been in effect in FY 2015 (that is, 45 percent of such LTCH cases would not have met the patient-level criteria for exclusion from the site neutral payment rate). Our Office of the Actuary estimates that the percent of LTCH PPS cases that will be paid at the site neutral payment rate in FY 2017 will not change significantly from the historical data. Taking into account the transitional blended payment rate and other proposed changes that would apply to the site neutral payment rate cases in FY 2017, we estimate that aggregate LTCH PPS payments for these site neutral payment rate cases would decrease by approximately 21 percent (or approximately $367 million).

Approximately 55 percent of LTCH cases are expected to meet the patient-level criteria for exclusion from the site neutral payment rate in FY 2017, and will be paid based on the LTCH PPS standard Federal payment rate for the full year. We estimate that total LTCH PPS payments for these LTCH PPS standard Federal payment rate cases in FY 2017 would increase approximately 0.3 percent (or approximately $12 million). This estimated increase in LTCH PPS payments for LTCH PPS standard Federal payment rate cases in FY 2017 is primarily due to the combined effects of the proposed 1.45 percent annual update to the LTCH PPS standard Federal payment rate for FY 2017 (discussed in section V.A. of the Addendum to this proposed rule) and an estimated decrease in HCO payments for these cases (discussed in section V.D.3. of the Addendum to this proposed rule).

Based on the 420 LTCHs that were represented in the FY 2015 LTCH cases that were used for the analyses in this proposed rule, we estimate that aggregate FY 2017 LTCH PPS payments would be approximately $4.757 billion, as compared to estimated aggregate FY 2016 LTCH PPS payments of approximately $5.112 billion, resulting in an estimated overall decrease in LTCH PPS payments of approximately $355 million. Because the combined distributional effects and estimated payment changes exceed $100 million, this proposed rule is a major economic rule. We note that this estimated $355 million decrease in LTCH PPS payments in FY 2017 (which includes estimated payments for LTCH PPS standard Federal payment rate cases and site neutral payment rate cases) does not reflect changes in LTCH admissions or case-mix intensity, which would also affect the overall payment effects of the proposals in this proposed rule.

The LTCH PPS standard Federal payment rate for FY 2016 is $41,762.85. For FY 2017, we are proposing an LTCH PPS standard Federal payment rate of $42,314.31, which reflects the proposed 1.45 percent annual update to the LTCH PPS standard Federal payment rate and the proposed area wage budget neutrality factor of 0.998723 to ensure that the proposed changes in the wage indexes and labor-related share do not influence aggregate payments. For LTCHs that fail to submit data for the LTCH QRP, in accordance with section 1886(m)(5)(C) of the Act, we are proposing an LTCH PPS standard Federal payment rate of $41,480.12. This proposed reduced LTCH PPS standard Federal payment rate reflects the updates previously described as well as the required 2.0 percentage point reduction to the annual update for failure to submit data under the LTCH QRP. We note that the factors previously described to determine the proposed FY 2017 LTCH PPS standard Federal payment rate are applied to the FY 2016 LTCH PPS standard Federal rate set forth under § 412.523(c)(3)(xi) (that is, $41,762.85).

Table IV shows the estimated impact for LTCH PPS standard Federal payment rate cases. The estimated change attributable solely to the proposed annual update to the LTCH PPS standard Federal payment rate is projected to result in an increase of 1.3 percent in payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017, on average, for all LTCHs (Column 6). In addition to the proposed annual update to the LTCH PPS standard Federal payment rate for FY 2017, the estimated increase of 1.3 percent shown in Column 6 of Table IV also includes estimated payments for SSO cases that will be paid using special methodologies that are not affected by the proposed annual update to the LTCH PPS standard Federal payment rate, as well as the reduction that is applied to the proposed annual update of LTCHs that do not submit the required LTCH QRP data. Therefore, for all hospital categories, the projected increase in payments based on the proposed LTCH PPS standard Federal payment rate to LTCH PPS standard Federal payment rate cases is somewhat less than the proposed 1.45 percent proposed annual update for FY 2017.

For FY 2017, we are proposing to update the wage index values based on the most recent available data, and we are proposing to continue to use labor market areas based on the OMB CBSA delineations (as discussed in section V.B. of the Addendum to this proposed rule). In addition, we are proposing an increase in the labor-related share from 62.0 percent to 66.6 percent under the LTCH PPS for FY 2017, based on the most recent available data on the relative importance of the labor-related share of operating and capital costs of the proposed 2013-based LTCH market basket (as discussed in section VII.D. of the preamble of this proposed rule). We also are proposing to apply an area wage level budget neutrality factor of 0.998723 to ensure that the proposed changes to the wage data and labor-related share do not result in a change in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases, which decreases the LTCH PPS standard Federal payment rate by approximately 0.13 percent.

We currently estimate total HCO payments for LTCH PPS standard Federal payment rate cases would decrease from FY 2016 to FY 2017. Based on the FY 2015 LTCH cases that were used for the analyses in this proposed rule, we estimate that the FY 2016 HCO threshold of $16,423 (as established in the FY 2016 IPPS/LTCH PPS final rule) would result in estimated HCO payments for LTCH PPS standard Federal payment rate cases in FY 2016 that are above the estimated 8 percent target. Specifically, we currently estimate that HCO payments for LTCH PPS standard Federal payment rate cases would be approximately 9.1 percent of the estimated total LTCH PPS standard Federal payment rate payments in FY 2016. Combined with our estimate that FY 2017 HCO payments for LTCH PPS standard Federal payment rate cases would be 8.0 percent of estimated total LTCH PPS standard Federal payment rate payments in FY 2017, this results in the estimated decrease in HCO payments of approximately 1.1 percent between FY 2016 and FY 2017.

In calculating these estimated HCO payments, we increased estimated costs by our actuaries' projected market basket percentage increase factor. This increase in estimated costs also results in a projected increase in SSO payments in FY 2017 (because 100 percent of the estimated cost of the case is an option in the SSO payment formula (§ 412.529)). We estimate that these increased SSO payments in FY 2017 would increase total payments for LTCH PPS standard Federal payment rate cases by approximately 0.25 percent. (Payments for SSO cases represent approximately 14 percent of the estimated total FY 2017 payments for LTCH PPS standard Federal payment rate cases.)

Table IV shows the estimated impact of the proposed payment rate and policy changes on LTCH PPS payments for LTCH PPS standard Federal payment rate cases for FY 2017 by comparing estimated FY 2016 LTCH PPS payments to estimated FY 2017 LTCH PPS payments. (As noted earlier, our analysis does not reflect changes in LTCH admissions or case-mix intensity.) The projected increase in payments from FY 2016 to FY 2017 for LTCH PPS standard Federal payment rate cases of 0.3 percent is attributable to the impacts of the change to the LTCH PPS standard Federal payment rate (1.3 percent in Column 6) and the effect of the estimated decrease in HCO payments for LTCH PPS standard Federal payment cases (−1.1 percent), and the estimated increase in payments for SSO cases (0.25 percent). We note that these impacts do not include LTCH PPS site neutral payment rate cases for the reasons discussed in section I.J.3. of this Appendix.

As we discuss in detail throughout this proposed rule, based on the most recent available data, we believe that the provisions of this proposed rule relating to the LTCH PPS, which are projected to result in an overall decrease in estimated aggregate LTCH PPS payments, and the resulting LTCH PPS payment amounts would result in appropriate Medicare payments that are consistent with the statute.

2. Impact on Rural Hospitals

For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. As shown in Table IV, we are projecting a 0.3 percent increase in estimated payments for LTCH PPS standard Federal payment rate cases. This estimated impact is based on the FY 2015 data for the 21 rural LTCHs (out of 420 LTCHs) that were used for the impact analyses shown in Table VI.

3. Anticipated Effects of Proposed LTCH PPS Payment Rate Changes and Policy Changes

a. Budgetary Impact

Section 123(a)(1) of the BBRA requires that the PPS developed for LTCHs "maintain budget neutrality." We believe that the statute's mandate for budget neutrality applies only to the first year of the implementation of the LTCH PPS (that is, FY 2003). Therefore, in calculating the FY 2003 standard Federal payment rate under § 412.523(d)(2), we set total estimated payments for FY 2003 under the LTCH PPS so that estimated aggregate payments under the LTCH PPS were estimated to equal the amount that would have been paid if the LTCH PPS had not been implemented.

Section 1886(m)(6)(A) of the Act establishes a dual rate LTCH PPS payment structure with two distinct payment rates for LTCH discharges beginning in FY 2016. Under this statutory change, LTCH discharges that meet the patient-level criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid based on the LTCH PPS standard Federal payment rate. LTCH discharges paid at the site neutral payment rate are generally paid the lower of the IPPS comparable per diem amount, including any applicable HCO payments, or 100 percent of the estimated cost of the case. The statute also establishes a transitional payment method for cases that are paid at the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 or FY 2017, under which the site neutral payment rate cases are paid based on a blended payment rate calculated as 50 percent of the applicable site neutral payment rate amount for the discharge and 50 percent of the applicable LTCH PPS standard Federal payment rate for the discharge.

As discussed in section I.J.1. of this Appendix, we project a decrease in aggregate LTCH PPS payments in FY 2017 of approximately $355 million. This estimated decrease in payments reflects the projected increase in payments to LTCH PPS standard Federal payment rate cases of approximately $12 million and the projected decrease in payments to site neutral payment rate cases of approximately $367 million under the dual rate LTCH PPS payment rate structure required by the statute beginning in FY 2016.

As discussed in section VII.B.7.b. of the preamble of this proposed rule, our actuaries project cost and resource changes for site neutral payment rate cases due to the site neutral payment rates required under the statute. Specifically, our actuaries project that the costs and resource use for cases paid at the site neutral payment rate will likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate, and will likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG. While we are able to incorporate this projection at an aggregate level into our payment modeling, because the historical claims data that we are using in this proposed rule to project estimated FY 2017 LTCH PPS payments (that is, FY 2015 LTCH claims data) do not reflect this actuarial projection, we are unable to model the impact of the change in LTCH PPS payments for site neutral payment rate cases at the same level of detail with which we are able to model the impacts of the changes to LTCH PPS payments for LTCH PPS standard Federal payment rate cases. Therefore, Table IV only reflects proposed changes in LTCH PPS payments for LTCH PPS standard Federal payment rate cases and, unless otherwise noted, the remaining discussion in section I.J.3. of this Appendix refers only to the impact on LTCH PPS payments for LTCH PPS standard Federal payment rate cases. In the following section, we present our provider impact analysis for the changes that affect LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

b. Impact on Providers

Under the dual rate LTCH PPS payment structure, there are two distinct payment rates for LTCH discharges occurring in cost reporting periods beginning on or after October 1, 2016. Under that statute, any discharges that occur on or after October 1, 2015, but prior to the start of the LTCH's FY 2016 cost reporting period, will be paid at the LTCH PPS standard Federal payment rate. On or after the start of an LTCH's FY 2017 cost reporting period, discharges are paid based on the nature of the case. As described previously, LTCH PPS standard Federal payment rate cases are defined as LTCH discharges that meet the patient-level criteria to be excluded from the typically lower site neutral payment rate, and site neutral payment rate cases are defined as LTCH discharges that do not meet the patient-level criteria and generally will be paid the lower site neutral payment rate. However, for discharges occurring in cost reporting periods beginning in FY 2016 or 2017, the statute specifies that site neutral payment rate cases are paid based on a transitional payment method that is calculated as 50 percent of the applicable site neutral payment rate amount and 50 percent of the applicable LTCH PPS standard Federal payment rate.

The basic methodology for determining a per discharge payment for LTCH PPS standard Federal payment rate cases is currently set forth under §§ 412.515 through 412.536. In addition to adjusting the LTCH PPS standard Federal payment rate by the MS–LTC–DRG relative weight, we make adjustments to account for area wage levels and SSOs. LTCHs located in Alaska and Hawaii also have their payments adjusted by a COLA. Under our application of the dual rate LTCH PPS payment structure, the LTCH PPS standard Federal payment rate is generally only used to determine payments for LTCH PPS standard Federal payment rate cases (that is, those LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate). LTCH discharges that do not meet the patient-level criteria for exclusion are paid the site neutral payment rate, which we are calculating as the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), including any applicable outlier payments, or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2). In addition, when certain thresholds are met, LTCHs also receive HCO payments for both LTCH PPS standard Federal payment rate cases and site neutral payment rate cases that are paid at the IPPS comparable per diem amount.

To understand the impact of the changes to the LTCH PPS payments for LTCH PPS standard Federal payment rate cases presented in this proposed rule on different categories of LTCHs for FY 2017, it is necessary to estimate payments per discharge for FY 2016 using the rates, factors, and the policies established in the FY 2016 IPPS/LTCH PPS final rule and estimate payments per discharge for FY 2017 using the rates, factors, and the policies proposed in this FY 2017 IPPS/LTCH PPS proposed rule (as discussed in section VII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule). As discussed elsewhere in this proposed rule, these estimates are based on the best available LTCH claims data and other factors, such as the application of inflation factors to estimate costs for SSO and HCO cases in each year. The resulting analyses can then be used to compare how our proposed policies applicable to LTCH PPS standard Federal payment rate cases affect different groups of LTCHs.

For the following analysis, we group hospitals based on characteristics provided in the OSCAR data, FY 2012 through FY 2013 cost report data in HCRIS, and PSF data. Hospital groups included the following:

- Location: Large urban/other urban/rural.
- Participation date.
- Ownership control.
- Census region.
- Bed size.

c. Calculation of LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases

For purposes of this impact analysis, to estimate the per discharge payment effects of our proposed policies on payments for LTCH PPS standard Federal payment rate cases, we simulated FYs 2016 and 2017 payments on a case-by-case basis using historical LTCH claims from the FY 2015 MedPAR files that would have met the criteria to be paid at the LTCH PPS standard Federal payment rate if the statutory patient-level criteria had been in effect at the time of discharge for those cases. For modeling FY 2016 LTCH PPS payments, we used the FY 2016 standard Federal payment rate of $41,762.85, or $40,941.55 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP. Similarly, for modeling payments based on the FY 2017 LTCH PPS standard Federal payment rate, we used the proposed FY 2017 standard Federal payment rate of $42,314.31, or $41,480.12 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP. In each case, we applied the applicable proposed adjustments for area wage levels and the COLA for LTCHs located in Alaska and Hawaii. Specifically, for modeling FY 2016 LTCH PPS payments, we used the current FY 2016 labor-related share (62.0 percent); the wage index values established in the Tables 12A through 12D listed in the Addendum to the FY 2016 IPPS/LTCH PPS final rule (which are available via the Internet on the CMS Web site); the FY 2016 HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases of $16,423 (as discussed in section V.D. of the Addendum to that final rule) and the FY 2016 COLA factors (shown in the table in section V.C. of the Addendum to that final rule) to adjust the FY 2016 nonlabor-related share (38.0 percent) for LTCHs located in Alaska and Hawaii. Similarly, for modeling FY 2017 LTCH PPS payments, we used the proposed FY 2017 LTCH PPS labor-related share (66.6 percent), the proposed FY 2017 wage index values from Tables 12A and 12B listed in section VI. of the Addendum to this proposed rule (which are available via the Internet on the CMS Web site), the proposed FY 2017 fixed-loss amount for LTCH PPS standard Federal payment rate cases of $22,728 (as discussed in section V.D.3. of the Addendum to this proposed rule), and the proposed FY 2017 COLA factors (shown in the table in section V.C. of the Addendum to this proposed rule) to adjust the proposed FY 2017 nonlabor-related share (33.4 percent) for LTCHs located in Alaska and Hawaii.

As previously discussed, our impact analysis reflects an estimated change in payments for SSO cases, as well as an estimated decrease in HCO payments for LTCH PPS standard Federal payment rate cases (as described previously in section I.J.1. of this Appendix). In modeling proposed payments for SSO and HCO cases for LTCH PPS standard Federal payment rate cases, we applied an inflation factor of 4.8 percent (determined by the Office of the Actuary) to update the 2015 costs of each case.

The impacts that follow reflect the estimated "losses" or "gains" among the various classifications of LTCHs from FY 2016 to FY 2017 based on the proposed payment rates and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this proposed rule. Table IV illustrates the estimated aggregate impact of the change in LTCH PPS payments for LTCH PPS standard Federal payment rate cases among various classifications of LTCHs. (As discussed previously, these impacts do not include LTCH PPS site neutral payment rate cases.)

- The first column, LTCH Classification, identifies the type of LTCH.
- The second column lists the number of LTCHs of each classification type.
- The third column identifies the number of LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria.
- The fourth column shows the estimated FY 2016 payment per discharge for LTCH

cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).

- The fifth column shows the estimated FY 2017 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).
- The sixth column shows the percentage change in estimated payments per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria from FY 2016 to FY 2017 due to the annual update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this proposed rule).
- The seventh column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017 for proposed changes to the area wage level adjustment (that is, the proposed wage indexes and the proposed labor-related share), including the application of the proposed area wage level budget neutrality factor (as discussed in section V.B. of the Addendum to this proposed rule).
- The eighth column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 (Column 4) to FY 2017 (Column 5) for all proposed changes (and includes the effect of estimated changes to HCO and SSO payments).

TABLE IV—IMPACT OF PROPOSED PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR STANDARD PAYMENT RATE CASES FOR FY 2017

[Estimated FY 2016 payments compared to estimated FY 2017 payments]

LTCH classification (1)	Number of LTCHs (2)	Number of LTCH PPS standard Federal payment rate cases (3)	Average FY 2016 LTCH PPS payment per case (4)	Proposed average FY 2017 LTCH PPS standard Federal payment rate payment per case[1] (5)	Proposed percent change in payments per case due to the annual update to the LTCH PPS standard Federal rate[2] (6)	Proposed percent change in payments per case due to changes to the area wage level adjustment with budget neutrality[3] (7)	Percent change in payments per case from FY 2016 to FY 2017 for all proposed changes[4] (8)
ALL PROVIDERS	420	72,064	$46,944	$47,105	1.3	0.0	0.3
BY LOCATION:							
RURAL	21	2,271	38,858	38,808	1.3	−0.6	0.2
URBAN	399	69,793	47,207	47,375	1.3	0.0	0.3
LARGE	202	41,448	49,428	49,738	1.3	0.2	0.3
OTHER	197	28,345	43,959	43,920	1.3	−0.3	0.2
BY PARTICIPATION DATE:							
BEFORE OCT. 1983	14	1,929	42,951	43,133	1.3	0.0	0.3
OCT. 1983–SEPT. 1993	42	8,856	53,153	53,438	1.2	0.3	0.4
OCT. 1993–SEPT. 2002	174	31,584	45,536	45,721	1.3	0.1	0.2
OCTOBER 2002 and AFTER	190	29,695	46,849	46,947	1.3	−0.2	0.2
BY OWNERSHIP TYPE:							
VOLUNTARY	78	10,016	47,838	47,719	1.3	−0.3	0.2
PROPRIETARY	325	60,366	46,633	46,844	1.3	0.1	0.3
GOVERNMENT	17	1,682	52,773	52,799	1.3	0.0	0.3
BY REGION:							
NEW ENGLAND	13	2,792	43,643	43,864	1.3	0.0	0.3
MIDDLE ATLANTIC	26	5,486	51,620	52,093	1.3	0.5	0.3
SOUTH ATLANTIC	63	12,021	46,804	46,754	1.3	−0.4	0.3
EAST NORTH CENTRAL	69	11,588	46,982	47,092	1.3	−0.2	0.2
EAST SOUTH CENTRAL	34	5,367	44,251	44,005	1.3	−0.8	0.2
WEST NORTH CENTRAL	29	3,877	46,850	46,623	1.3	−0.4	0.2
WEST SOUTH CENTRAL	128	18,590	42,312	42,344	1.3	−0.1	0.2
MOUNTAIN	33	4,287	49,026	49,174	1.3	0.2	0.2
PACIFIC	25	8,056	56,476	57,556	1.2	1.2	0.4
BY BED SIZE:							
BEDS: 0–24	26	1,497	43,923	44,126	1.3	−0.1	0.2
BEDS: 25–49	194	24,575	44,012	44,018	1.3	−0.4	0.2
BEDS: 50–74	119	19,597	48,823	48,938	1.3	0.1	0.3
BEDS: 75–124	48	12,941	49,992	50,356	1.3	0.3	0.3
BEDS: 125–199	23	8,347	46,472	46,688	1.3	0.1	0.3
BEDS: 200 +	10	5,107	47,771	48,242	1.2	0.4	0.3

[1] Estimated proposed FY 2017 LTCH PPS payments for LTCH PPS standard Federal payment rate criteria based on the proposed payment rate and factor changes applicable to such cases presented in the preamble of and the Addendum to this proposed rule.

[2] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017 for the proposed annual update to the LTCH PPS standard Federal payment rate. The temporary exclusion from the site neutral payment rate provided by section 231 of Public Law 114–113 is not reflected in these estimated FY 2017 LTCH PPS payments.

[3] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017 for proposed changes to the area wage level adjustment under § 412.525(c) (as discussed in section V.B. of the Addendum to this proposed rule).

[4] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 (shown in Column 4) to FY 2017 (shown in Column 5), including all of the proposed changes to the rates and factors applicable to such cases presented in the preamble and the Addendum to this proposed rule. We note that this column, which shows the percent change in estimated payments per discharge for all proposed changes, does not equal the sum of the percent changes in estimated payments per discharge for the proposed annual update to the LTCH PPS standard Federal payment rate (Column 6) and the proposed changes to the area wage level adjustment with budget neutrality (Column 7) due to the effect of estimated changes in both estimated payments to SSO cases that are paid based on estimated costs and aggregate HCO payments for LTCH PPS standard Federal payment rate cases (as discussed in this impact analysis), as well as other interactive effects that cannot be isolated.

d. Results

Based on the FY 2015 LTCH cases (from 420 LTCHs) that were used for the analyses in this proposed rule, we have prepared the following summary of the impact (as shown in Table IV) of the proposed LTCH PPS payment rate and proposed policy changes for LTCH PPS standard Federal payment rate cases presented in this proposed rule. The impact analysis in Table IV shows that estimated payments per discharge for LTCH PPS standard Federal payment rate cases are expected to increase 0.3 percent, on average, for all LTCHs from FY 2016 to FY 2017 as a result of the proposed payment rate and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this proposed rule. This estimated 0.3 percent increase in LTCH PPS payments per discharge was determined by comparing estimated FY 2017 LTCH PPS payments (using the proposed payment rates and factors discussed in this proposed rule) to estimated FY 2016 LTCH PPS payments for LTCH discharges which would be LTCH PPS standard Federal payment rate cases if the dual rate LTCH PPS payment structure had been in effect at the time of the discharge (as described in section I.J.3. of this Appendix).

As stated previously, we are proposing to update the LTCH PPS standard Federal payment rate for FY 2017 by 1.45 percent based on the estimate of the proposed 2013-based LTCH PPS market basket increase (2.7 percent), the proposed reduction of 0.5 percentage point for the MFP adjustment, and the 0.75 percentage point reduction consistent with sections 1886(m)(3) and (m)(4) of the Act. For LTCHs that fail to submit quality data under the requirements of the LTCH QRP, as required by section 1886(m)(5)(C) of the Act, a 2.0 percentage point reduction is applied to the proposed annual update to the LTCH PPS standard Federal payment rate. As explained earlier in this section, for most categories of LTCHs (as shown in Table IV, Column 6), the estimated payment increase due to the 1.45 percent proposed annual update to the LTCH PPS standard Federal payment rate is projected to result in approximately a 1.3 percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases for all LTCHs from FY 2016 to FY 2017. This is because our estimate of the changes in payments due to the proposed update to the LTCH PPS standard Federal payment rate also reflects estimated payments for SSO cases that are paid using special methodologies that are not affected by the proposed update to the LTCH PPS standard Federal payment rate. Consequently, for certain hospital categories, we estimate that payments to LTCH PPS standard Federal payment rate cases may increase by less than 1.45 percent due to the proposed annual update to the LTCH PPS standard Federal payment rate for FY 2017.

(1) Location

Based on the most recent available data, the vast majority of LTCHs are located in urban areas. Only approximately 5 percent of the LTCHs are identified as being located in a rural area, and approximately 3 percent of all LTCH PPS standard Federal payment rate cases are expected to be treated in these rural hospitals. The impact analysis presented in Table IV shows that the overall average percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017 for all hospitals is 0.3 percent. For rural LTCHs, the overall percent change for LTCH PPS standard Federal payment rate cases is estimated to be a 0.2 percent increase, while for urban LTCHs, we estimate the increase will be 0.3 percent. Large urban LTCHs are projected to experience an increase of 0.3 percent in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017, and other urban LTCHs are projected to experience an increase of 0.2 percent in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017, as shown in Table IV.

(2) Participation Date

LTCHs are grouped by participation date into four categories: (1) Before October 1983; (2) between October 1983 and September 1993; (3) between October 1993 and September 2002; and (4) October 2002 and after. Based on the most recent available data, the categories of LTCHs with the largest expected percentage of LTCH PPS standard Federal payment rate cases (approximately 44 percent) are in LTCHs that began participating in the Medicare program between October 1993 and September 2002, and they are projected to experience a 0.2 percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017, as shown in Table IV.

Approximately 3.3 percent of LTCHs began participating in the Medicare program before October 1983, and these LTCHs are projected to experience an average percent increase (0.3 percent) in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017, as shown in Table IV. Approximately 10 percent of LTCHs began participating in the Medicare program between October 1983 and September 1993. These LTCHs are projected to experience a larger than average increase (0.4 percent) in estimated payments for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017, which is primarily due to a projected larger than average increase in payments due to the proposed changes to the area wage adjustment. LTCHs that began participating in the Medicare program after October 1, 2002, which treat approximately 41 percent of all LTCH PPS standard Federal payment rate cases, are projected to experience a 0.2 percent increase in estimated payments from FY 2016 to FY 2017.

(3) Ownership Control

LTCHs are grouped into three categories based on ownership control type: Voluntary, proprietary, and government. Based on the most recent available data, approximately 19 percent of LTCHs are identified as voluntary (Table IV). The majority (approximately 77 percent) of LTCHs are identified as proprietary, while government owned and operated LTCHs represent approximately 4 percent of LTCHs. Based on ownership type, voluntary LTCHs are expected to experience an average increase in payments to LTCH PPS standard Federal payment rate cases of 0.2 percent. Both proprietary and government owned and operating LTCHs are expected to experience an increase of 0.3 percent in payments to LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017.

(4) Census Region

Estimated payments per discharge for LTCH PPS standard Federal payment rate cases for FY 2017 are projected to increase for LTCHs located in all regions in comparison to FY 2016. Of the 9 census regions, we project that the increase in estimated payments per discharge to LTCH PPS standard Federal payment rate cases would have the largest positive impact on LTCHs in the Pacific region (0.4 percent as shown in Table IV), which is largely attributable to the proposed changes in the area wage level adjustment.

In contrast, LTCHs located in the East North Central, East South Central, West North Central, West South Central, and Mountain regions are projected to experience the smallest increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017. The lower than national average estimated increase in payments of 0.2 percent is primarily due to estimated decreases in payments associated with the proposed changes to the area wage level adjustment.

(5) Bed Size

LTCHs are grouped into six categories based on bed size: 0–24 beds; 25–49 beds; 50–74 beds; 75–124 beds; 125–199 beds; and greater than 200 beds. All bed size categories are projected to receive an increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017. We project that LTCHs with 50 or more beds (that is, LTCHs in the 50–74 beds; 75–124 beds; 125–199 beds; and 200+ beds categories) would experience an average increase in payments for LTCH PPS standard Federal payment rate cases (0.3 percent). LTCHs with less than 50 beds (that is, LTCHs in the 0–24 beds and 25–49 beds categories) are expected to experience a smaller than average increase in payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2016 to FY 2017 (0.2 percent), mostly due to estimated decreases in payments from the proposed area wage level adjustment.

4. Effect on the Medicare Program

As stated previously, we project that the provisions of this proposed rule would result in an increase in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases in FY 2017 relative to FY 2016 of approximately $12 million (or approximately 0.3 percent) for the 420 LTCHs in our database. Although, as stated previously, the hospital-level impacts do not include LTCH PPS site neutral payment rate cases, we estimate that the provisions of this proposed rule would result in a decrease in estimated aggregate LTCH PPS payments to site neutral payment rate cases in FY 2017 relative to FY 2016 of approximately $367million (or approximately 21 percent) for the 420 LTCHs in our database. Therefore, we project that the provisions of this proposed rule would result in a decrease in estimated aggregate LTCH PPS payments to all LTCH cases in FY 2017 relative to FY 2016 of approximately $355 million (or approximately 6.9 percent) for the 420 LTCHs in our database.

5. Effect on Medicare Beneficiaries

Under the LTCH PPS, hospitals receive payment based on the average resources consumed by patients for each diagnosis. We do not expect any changes in the quality of care or access to services for Medicare beneficiaries as a result of this proposed rule, but we continue to expect that paying prospectively for LTCH services will enhance the efficiency of the Medicare program.

K. Effects of Proposed Requirements for the Hospital Inpatient Quality Reporting (IQR) Program

In section VIII.A. of the preamble of this proposed rule, we discuss our requirements for hospitals to report quality data under the Hospital IQR Program in order to receive the full annual percentage increase for the FY 2019 payment determination.

In section VIII.A.3.b. of the preamble of this proposed rule, we are proposing to remove 15 measures: 13 eCQMs (2 of which we are proposing to remove also in their chart-abstracted form) and 2 structural measures.

We are proposing to remove the electronic versions of: (1) AMI–2: Aspirin Prescribed at Discharge for AMI (NQF #0142); (2) AMI–7a: Fibrinolytic Therapy Received Within 30 minutes of Hospital Arrival; (3) AMI–10: Statin Prescribed at Discharge; (4) HTN: Healthy Term Newborn (NQF #0716); (5) PN–6: Initial Antibiotic Selection for Community-Acquired Pneumonia (CAP) in Immunocompetent Patients (NQF #0147); (6) SCIP-Inf-1a: Prophylactic Antibiotic Received within 1 Hour Prior to Surgical Incision (NQF #0527); (7) SCIP-Inf-2a: Prophylactic Antibiotic Selection for Surgical Patients (NQF #0528); (8) SCIP Inf-9: Urinary Catheter Removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with Day of Surgery Being Day Zero; (9) STK–4: Thrombolytic Therapy (NQF #0437); (10) VTE–3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy (NQF #0373); (11) VTE–4: Venous Thromboembolism Patients Receiving Unfractionated Heparin (UFH) with Dosages/Platelet Count Monitoring by Protocol (or Nomogram); (12) VTE–5: Venous Thromboembolism Discharge Instructions; and (13) VTE–6: Incidence of Potentially Preventable Venous Thromboembolism.

We are also proposing to remove: (1) STK–4: Thrombolytic Therapy (NQF #0437); and (2) VTE–5: Venous Thromboembolism Discharge Instructions in their chart-abstracted form. Finally, we are also proposing to remove two structural measures: (1) Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care; and (2) Participation in a Systematic Clinical Database Registry for General Surgery.

As further explained in section X.B.6. of the preamble of this proposed rule, we believe that there would be a reduction in burden for hospitals due to the removal of two chart-abstracted measures (STK–4 and VTE–5). Due to the burden associated with the collection of chart-abstracted data, we estimate that the removal of STK–4 would result in a burden reduction of approximately 303,534 hours across all hospitals participating in the Hospital IQR Program for the FY 2019 payment determination. We estimate that the removal of VTE–5 would result in a burden reduction of approximately 653,565 hours across all hospitals participating in the Hospital IQR Program for the FY 2019 payment determination. We believe that removing 13 eCQMs would reduce burden for hospitals, however, if our proposal to require hospitals to submit data on all of the available eCQMs included in the Hospital IQR Program measure set is finalized as proposed, this modest reduction in burden would be offset by the increased burden associated with submitting data on 15 eCQMs instead of 4 eCQMs. We believe that there would be a negligible burden reduction due to the removal of the two structural measures.

Also, we are proposing refinements to two previously adopted measures: (1) Expanding the population cohort for the Hospital-Level, Risk-Standardized 30-Day Episode-of-Care Payment Measure for Pneumonia; and (2) Patient Safety and Adverse Events Composite (NQF #0531). As further explained in section X.B.6. of the preamble of this proposed rule, we believe no additional burden on hospitals will result from the proposed refinements to these two claims-based measures.

In addition, we are proposing to add four claims-based measures to the Hospital IQR Program measure set beginning with the FY 2019 payment determination: (1) Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure; (2) Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure; (3) Spinal Fusion Clinical Episode-Based Payment Measure; and (4) Excess Days in Acute Care after Hospitalization for Pneumonia. We believe no additional burden on hospitals would result from the addition of these four proposed claims-based measures.

For the FY 2019 payment determination and subsequent years, we are proposing to require hospitals to submit data for all available eCQMs included in the Hospital IQR Program measure set in a manner that will permit eligible hospitals to align Hospital IQR Program requirements with some requirements under the Medicare and Medicaid EHR Incentive Programs. Specifically, hospitals would be required to submit a full calendar year of data for all eCQMs, on an annual basis beginning with CY 2017 reporting for the FY 2019 payment determination, as further explained in section X.B.6. of the preamble of this proposed rule. In total, we expect that this proposal would increase burden by 30,800 hours across all hospitals participating in the Hospital IQR Program.

As we noted in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49763), for validation of chart-abstracted data, we require hospitals to provide 72 charts per hospital per year (with an average page length of 1,500), including 40 charts for HAI validation and 32 charts for clinical process of care validation, for a total of 108,000 pages per hospital per year. We reimburse hospitals at 12 cents per photocopied page for a total per hospital cost of $12,960. For hospitals providing charts digitally via a re-writable disc, such as encrypted CD–ROMs, DVDs, or flash drives, we will reimburse hospitals at a rate of 40 cents per disc, and additionally hospitals will be reimbursed $3.00 per record. For hospitals providing charts via secure file transfer, we will reimburse hospitals at a rate of $3.00 per record. We will maintain these requirements for the FY 2019 payment determination and subsequent years.

In this proposed rule, we are proposing to modify the existing validation process for Hospital IQR Program data to include a random sample of up to 200 hospitals for validation of eCQMs in the Hospital IQR Program. As further explained in section X.B.5. of the preamble of this proposed rule, we estimate that 43 hours of work for up to 200 hospitals reflects a total burden increase of 8,533 labor hours. As such, we estimate an hourly labor cost of $32.84 and a cost increase of $280,224 (8,533 additional burden hours × $32.84 per hour) across the up to 200 hospitals selected for eCQM validation, on an annual basis.

Finally, we are proposing to update our Extraordinary Circumstances Extensions or Exemptions (ECE) policy. We believe the proposed updates would have no effect on burden for hospitals.

Historically, 100 hospitals, on average, that participate in the Hospital IQR Program do not receive the full annual percentage increase in any fiscal year due to the requirements of this program. We anticipate that, because of the new requirements for reporting we are proposing for the FY 2019 payment determination, the number of hospitals not receiving the full annual percentage increase may be higher than average. At this time, information is not available to determine the precise number of hospitals that would not meet the proposed requirements to receive the full annual percentage increase for the FY 2019 payment determination. If the number of hospitals failing to receive the full annual percentage increase does increase because of the new requirements, we anticipate that, over the long run, this number would decline as hospitals gain more experience with these requirements.

Under OMB number 0938–1022, considering the policies proposed above, we estimate a total burden decrease of 917,766 hours, at a total cost decrease of approximately $30 million across approximately 3,300 hospitals participating in the Hospital IQR Program for the FY 2019 payment determination. In implementing the Hospital IQR Program and other quality reporting programs, we have focused on measures that have high impact and support CMS and HHS priorities for improved quality and efficiency of care for Medicare beneficiaries.

L. Effects of Proposed Requirements for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

In section VIII.B. of the preamble of this proposed rule, we discuss our policies for the quality data reporting program for PPS-exempt cancer hospitals (PCHs), which we refer to as the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. The PCHQR Program is authorized under section 1866(k) of the Act, which was added by section 3005 of the Affordable Care Act.

In section VIII.B.3. of the preamble of this proposed rule, we are proposing updates to one of the measures on which PCHs currently submit data: Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382). In addition, in section VIII.B.4.b. of the preamble of this proposed rule, we are proposing the addition of one claims-based quality measure for the PCHQR Program: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy.

The impact of the proposed new requirements for the PCHQR Program is expected to be minimal overall since beginning with Q1 2016 events, PCHs have been reporting Clinical Process/Oncology Care Measures using a sampling methodology which requires reporting no more than 25 cases per facility (79 FR 28259). As the measure cohort expansion for Oncology: Radiation Dose Limits to Normal Tissues (NQF #0382) does not expand the maximum required sample, we do not anticipate that this cohort expansion will significantly impact the operational burden for PCHs.

In addition, the Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy measure is a claims-based measure and, therefore, poses no additional burden for PCHs to submit data beyond that which they currently submit as part of the claims process.

One expected effect of the PCHQR Program is to keep the public informed of the quality of care provided by PCHs. We will display publicly the quality measure data collected under the PCHQR Program as required under the Act. These data will be displayed on the *Hospital Compare* Web site. The goals of making these data available to the public in a user-friendly and relevant format include, but are not limited to: (1) Allowing the public to compare PCHs in order to make informed health care decisions regarding care setting; and (2) providing information about current trends in health care. Furthermore, PCHs can use their own health care quality data for many purposes such as in risk management programs, healthcare associated infection prevention programs, and research and development activities, among others.

M. Effects of Proposed Requirements for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP) for the FY 2018 Payment Determination and Subsequent Years

In section VIII.C.1. of the preamble of this proposed rule, we discuss the implementation of section 1886(m)(5) of the Act, which was added by section 3004(a) of the Affordable Care Act. Section 1886(m)(5) of the Act provides that, for rate year 2014 and each subsequent year, any LTCH that does not submit data to the Secretary in accordance with section 1886(m)(5)(C) and (F) of the Act shall receive a 2 percentage point reduction to the annual update to the standard Federal rate for discharges for the hospital during the applicable fiscal year.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49838 through 49839), we estimated that only a few LTCHs will not receive the full annual percentage increase in any fiscal year as a result of failure to submit data under the LTCH QRP. There are approximately 432 LTCHs currently reporting quality data to CMS. At the time that this analysis was prepared, 39, or approximately 9.5 percent, of 412 eligible LTCHs were determined to be noncompliant and therefore will receive a 2 percentage point reduction to their FY 2016 annual payment update.

Information is not available to determine the precise number of LTCHs that will not meet the requirements to receive the full annual percentage increase for the FY 2017 payment determination.

We believe that a majority of LTCHs will continue to collect and submit data for the FY 2017 payment determination and subsequent years because they will continue to view the LTCH QRP as an important step in improving the quality of care patients receive in the LTCHs. We believe that the burden associated with the LTCH QRP is the time and effort associated with data collection.

Currently, LTCHs use two separate data collection mechanisms to report quality data to CMS: The CDC's NHSN, which is used to report all Healthcare Associated Infections (HAI) (CAUTI, CLABSI, MRSA Bacteremia, CDI, VAE) and vaccination data, (Influenza Vaccination Coverage Among Healthcare Personnel measure); and the LTCH CARE Data Set, which is submitted to the QIES ASAP system.

The data collection burden associated with reporting quality measures via the CDC's NHSN is discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49838 through 49839). These measures are stewarded by the CDC, and the reporting burden is approved under OMB control number 0920–0666.

The All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from Long-Term Care Hospitals (NQF #2512) measure is calculated based on Medicare FFS claims data, and therefore does not have any associated data reporting burden for LTCHs.

The remaining assessment-based quality measure data are reported to CMS by LTCHs using the LTCH CARE Data Set. As of April 1, 2016, LTCHs use the LTCH CARE Data Set Version 3.00 (approved under OMB control number 0938–1163) which includes data elements related to the following quality measures: Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (NQF #0678), Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) (NQF #0680); Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674); Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631); Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631); and Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632).

In this proposed rule, we are retaining 13 previously finalized quality measures and are proposing 4 additional measures for use in the LTCH QRP. In section VII.C.6. of the preamble of this proposed rule, we are proposing three measures for the FY 2018 payment determination and subsequent years: (1) MSPB–PAC LTCH QRP; (2) Discharge to Community—PAC LTCH QRP; and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for the PAC LTCH QRP. These three measures are Medicare claims-based measures, and because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes, we believe there would be no additional burden if any of these measures are finalized.

In section VIII.C.9.d. of the preamble of this proposed rule, we are proposing to expand the data collection timeframe for the measure NQF #0680 Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (77 FR 53624 through 53627), beginning with the FY 2019 payment determination. The data collection time frame and associated data submission deadlines are currently aligned with the Influenza Vaccination Season (IVS) (October 1 of a given year through March 31 of the subsequent year), and only require data collection during the two calendar year quarters that align with the IVS. We have proposed to expand the data collection timeframe from just two quarters (covering the IVS) to a full four quarters or 12 months. We refer readers to section VIII.C.9.d. of the preamble of this proposed rule for further details on the proposed expansion of data collection for this measures (NQF #0680), including data collection timeframes and associated submission deadlines. We originally finalized this measure for use in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53624 through 53627). Although we finalized data collection for this measure to coincide with the IVS, we originally proposed year-round data collection. The associated PRA package, which was approved under OMB control number 0938–1163, included burden calculations that aligned with our original proposal for year-round data collection. All subsequent PRA packages, and the PRA package that is currently under review by OMB, included burden calculations reflecting year-round (12 month) data collection for this measure. Because of this, the proposed change in the data collection timeframe for this measure, and any associated burden related to increased data collection, has already been accounted for in the total burden figures included in this section of the preamble of this proposed rule.

In section VIII.C.7. of the preamble of this proposed rule, we are proposing to adopt one measure for the FY 2020 payment determination and subsequent years: Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC LTCH QRP. In addition, we are proposing that data for this measure will be collected and reported using the LTCH CARE Data Set Version 4.00 (effective April 1, 2018).

While reporting quality measure data involves collecting information, we believe that the burden associated with modifications to the LTCH CARE Data Set discussed in this proposed rule fall under the PRA exceptions provided in section 1899B(m) of the Act. Section 1899B(m) of the Act, which was added by the IMPACT Act, states that the PRA requirements do not apply to section 1899B of the Act and the sections referenced in section 1899B(a)(2)(B) of the Act that require modifications in order to achieve standardized patient assessment data. However, the PRA requirements and burden estimates will be submitted to OMB for review and approval when modifications to the LTCH CARE Data Set or other applicable PAC assessment instruments are not used to achieve standardized patient assessment data.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49838 through 49840), we discussed burden estimates for the 13 previously finalized quality measures which we are retaining in this proposed rule using the LTCH CARE Data Set Version 2.01. Based on a revised PRA package for the LTCH CARE Data Set Version 3.00, we estimate the total cost for the previously finalized assessment-based measures was $13,929 per LTCH annually or $6,017,146 for all LTCHs annually. In addition, we estimate that the cost to report the previously finalized quality measures via the CDC's NHSN was $10,896 per LTCH annually or $4,706,857 for all LTCHs annually. The revised total estimate for all 13 previously finalized measures was $24,825 per LTCH annually or $10,724,003 for all LTCHs annually. The two estimates discussed above, as well as the comprehensive estimate discussed below, include overhead; however, obtaining data on other overhead costs is challenging. Overhead costs vary greatly across industries and firm sizes. In addition, the precise cost elements assigned as "indirect" or "overhead" costs, as opposed to direct costs or employee wages, are subject to some interpretation at the firm level. Therefore, we have chosen to calculate the cost of overhead at 100 percent of the mean hourly wage. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Because we are proposing to add the Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC LTCH QRP measure in the LTCH CARE Data Set Version 4.00, the estimated burden and cost would increase if this measure is finalized. The additional data elements for this proposed quality measure will take 6 minutes of nursing/clinical staff time to report data on admission and 4 minutes of nursing/clinical staff time to report data on discharge, for a total of 10 minutes. We believe that the additional LTCH CARE Data Set items we are proposing would be completed by registered nurses and pharmacists. As a result, we estimate that the total cost related to the proposed Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC LTCH QRP measure would be $3,080 per LTCH annually, or $1,330,721 for all LTCHs annually. Because the three measures proposed in section VII.C.6. of the preamble of this proposed rule are claims-based and would be calculated based on data that are already reported to the Medicare program for payment purposes, we believe that there would be no additional LTCH burden if any of these measures is finalized.

Overall, we estimate the total cost for the 13 previously adopted measures and the 4 proposed measures would be $27,905 per LTCH annually or $12,054,724 for all LTCHs annually. This is an average increase of 14 percent to all LTCHs over the burden discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49838 through 49840), which included all quality measures that LTCHs are required to report under the LTCH QRP, with the exception of those 4 new measures we are proposing in this proposed rule.

We intend to continue to closely monitor the effects of the LTCH QRP on LTCHs and help facilitate successful reporting outcomes through ongoing stakeholder education, national trainings, LTCH announcements, Web site postings, CMS Open Door Forums, and general and technical help desks.

N. Effects of Proposed Updates to the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program

As discussed in section VIII.D. of the preamble of this proposed rule and in accordance with section 1886(s)(4)(A)(i) of the Act, we will implement a 2.0 percentage point reduction in the FY 2019 market basket update for IPFs that have failed to comply with the IPFQR Program requirements for FY 2019, including reporting on the required measures. In section VIII.D. of the preamble of this proposed rule, we discuss how the 2 percentage point reduction will be applied. For FY 2016, of the 1,684 IPFs eligible for the IPFQR Program, 51 did not receive the full market basket update because of the IPFQR Program; 24 of these IPFs chose not to participate and 27 did not meet the requirements of the program. We anticipate that even fewer IPFs will receive the reduction for FY 2017 as IPFs become more familiar with the requirements. Thus, we estimate that this policy will have a negligible impact on overall IPF payments for FY 2017.

Based on the proposals in this proposed rule, we estimate a total increase in burden due to the proposed addition of a chart-abstracted measure set of 212 hours per IPF or 357,008 hours across all IPFs, resulting in a total increase in financial burden of approximately $6,962 per IPF or $11,724,143 across all IPFs. We also estimate a total increase in burden for training of 2 hours per IPF or 3,368 hours across all IPFs, resulting in a total increase in financial burden of $65.68 per IPF or $110,605 across all IPFs. Our estimate for the total increase in burden, including the newly proposed chart-abstracted measure set and training, is 360,376 hours across all IPFs, which at $32.84 labor cost per hour, totals $11,834,748. As discussed in section X.B.10. of the preamble of this proposed rule, we will attribute the costs associated with the finalized proposals to the year in which these costs begin; for the purposes of all the proposed changes made in this proposed rule, that year is FY 2017. Further information on these estimates can be found in section X.B.10. of the preamble of this proposed rule.

We intend to closely monitor the effects of this quality reporting program on IPFs and help facilitate successful reporting outcomes through ongoing stakeholder education, national trainings, and a technical help desk.

O. Effects of Proposed Requirements Regarding Electronic Health Record (EHR) Meaningful Use Program

In section VIII.E. of the preamble of this proposed rule, we discuss proposed requirements for the Medicare and Medicaid EHR Incentive Programs. We are proposing CQM reporting requirements, including reporting periods and submission periods, as well as CQMs required and information about CQM specifications' updates, for the Medicare and Medicaid EHR Incentive Programs for eligible hospitals and CAHs for 2017. We note that these proposals would only apply for eligible hospitals and CAHs submitting CQMs electronically in CY 2017. Because these proposals for data collection would align with the reporting requirements in place for the Hospital IQR Program and eligible hospitals and CAHs still have the option to submit their clinical quality measures via attestation for the Medicare and Medicaid EHR Incentive Programs, we do not believe these proposals would have a significant impact.

P. Alternatives Considered

This proposed rule contains a range of proposed policies. It also provides descriptions of the statutory provisions that are addressed, identifies the proposed policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

Q. Overall Conclusion

1. Acute Care Hospitals

Table I of section I.G. of this Appendix demonstrates the estimated distributional impact of the IPPS budget neutrality requirements for the proposed MS–DRG and wage index changes, and for the wage index reclassifications under the MGCRB. Table I also shows a projected overall increase of 0.7 percent in operating payments. As discussed in section I.G. of this Appendix, we estimate that operating payments would increase by approximately $693 million in FY 2017 relative to FY 2016. However, when we account for the impact of the proposed changes in Medicare DSH payments and the impact of the proposed additional payments based on uncompensated care in accordance with section 3133 of the Affordable Care Act, based on estimates provided by the CMS Office of the Actuary, consistent with our policy discussed in section IV.F. of the preamble of this proposed rule, we estimate that operating payments would increase by approximately $525 million relative to FY 2016. We currently estimate that the proposed changes in new technology add-on payments for FY 2017 would decrease spending by approximately $50 million due to the expiration of new technology add-on payments for four technologies. In addition, the proposed changes to the Hospital Readmissions Reduction Program for FY 2017 would decrease spending by $100 million, as a result of the proposed inclusion of the refinement to the pneumonia readmissions measure that expanded the measure cohort, along with the addition of the CABG readmission measure, in the calculation of the FY 2017 payment adjustment factor. This estimate, combined with our estimated increase in FY 2017 operating payment of $525 million, would result in an estimated increase of approximately $375 million for FY 2017. We estimate that hospitals would experience a 2.0 percent increase in capital payments per case, as shown in Table III of section I.I. of this Appendix. We project that there would be a $164 million increase in capital payments in FY 2017 compared to FY 2016. The cumulative operating and capital payments would result in a net increase of approximately $539 million to IPPS providers. The discussions presented in the previous pages, in combination with the rest of this proposed rule, constitute a regulatory impact analysis.

2. LTCHs

Overall, LTCHs are projected to experience a decrease in estimated payments per discharge in FY 2017. In the impact analysis, we are using the proposed rates, factors, and policies presented in this proposed rule, including updated wage index values and relative weights, and the best available claims and CCR data to estimate the change in payments under the LTCH PPS for FY 2017. Accordingly, based on the best available data for the 420 LTCHs in our database, we estimate that FY 2017 LTCH PPS payments would decrease approximately $355 million relative to FY 2016 as a result of the proposed payment rates and factors presented in this proposed rule.

II. Accounting Statements and Tables

A. Acute Care Hospitals

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in the following Table V, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate to acute care hospitals. This table provides our best estimate of the change in Medicare payments to providers as a result of the proposed changes to the IPPS presented in this proposed rule. All expenditures are classified as transfers to Medicare providers.

The costs to the Federal Government associated with the proposed policies in this proposed rule are estimated at $539 million.

TABLE V—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES UNDER THE IPPS FROM FY 2016 TO FY 2017

Category	Transfers
Annualized Monetized Transfers.	$539 million.
From Whom to Whom.	Federal Government to IPPS Medicare Providers.

B. LTCHs

As discussed in section I.J. of this Appendix, the impact analysis of the proposed payment rates and factors presented in this proposed rule under the LTCH PPS is projected to result in a decrease in estimated aggregate LTCH PPS payments in FY 2017 relative to FY 2016 of approximately $355 million based on the data for 420 LTCHs in our database that are subject to payment under the LTCH PPS. Therefore, as required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table VI, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate to the proposed changes to the LTCH PPS. Table VI provides our best estimate of the estimated change in Medicare payments under the LTCH PPS as a result of the proposed payment rates and factors and other provisions presented in this proposed rule based on the data for the 420 LTCHs in our database. All expenditures are classified as transfers to Medicare providers (that is, LTCHs).

The savings to the Federal Government associated with the policies for LTCHs in this proposed rule are estimated at $355 million.

TABLE VI—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FROM THE FY 2016 LTCH PPS TO THE FY 2017 LTCH PPS

Category	Transfers
Annualized Monetized Transfers.	−$355 million.
From Whom to Whom.	Federal Government to LTCH Medicare Providers

III. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.5 million to $38.5 million in any 1 year). (For details on the latest standards for health care providers, we refer readers to page 36 of the Table of Small Business Size Standards for NAIC 622 found on the SBA Web site at: *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.*)

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity. We believe that the provisions of this proposed rule relating to acute care hospitals would have a significant impact on small entities as explained in this Appendix. Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary LTCHs. Therefore, we are assuming that all LTCHs are considered small entities for the purpose of the analysis in section I.J. of this Appendix. MACs are not considered to be small entities. Because we acknowledge that many of the affected entities are small entities, the analysis discussed throughout the preamble of this proposed rule constitutes our regulatory flexibility analysis. In this proposed rule, we are soliciting public comments on our estimates and analysis of the impact of our proposals on those small entities. Any public comments that we receive and our responses will be presented in the final rule.

IV. Impact on Small Rural Hospitals

Section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis for any proposed or final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Thus, for purposes of the IPPS and the LTCH PPS, we continue to classify these hospitals as urban hospitals. (We refer readers to Table I in section I.G. of this Appendix for the quantitative effects of the proposed policy changes under the IPPS for operating costs.)

V. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold level is approximately $146 million. This proposed rule would not mandate any requirements for State, local, or tribal governments, nor would it affect private sector costs.

VI. Executive Order 12866

In accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget reviewed this proposed rule.

Appendix B: Recommendation of Update Factors for Operating Cost Rates of Payment for Inpatient Hospital Services

I. Background

Section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Under section 1886(e)(5) of the Act, we are required to publish update factors recommended by the Secretary in the proposed and final IPPS rules, respectively. Accordingly, this Appendix provides the recommendations for the update factors for the IPPS national standardized amount, the hospital-specific rate for SCHs and MDHs, and the rate-of-increase limits for certain hospitals excluded from the IPPS, as well as LTCHs. In prior years, we have made a recommendation in the IPPS proposed rule and final rule for the update factors for the payment rates for IRFs and IPFs. However, for FY 2017 consistent with approach for FY 2016, we are including the Secretary's recommendation for the update factors for IRFs and IPFs in separate **Federal Register** documents at the time that we announce the annual updates for IRFs and IPFs. We also discuss our response to MedPAC's recommended update factors for inpatient hospital services.

II. Inpatient Hospital Update for FY 2017

A. Proposed FY 2017 Inpatient Hospital Update

As discussed in section IV.B. of the preamble to this proposed rule, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act and a reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful electronic health record (EHR) users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then subject to an adjustment based on changes in economy-wide productivity (the multifactor productivity (MFP) adjustment), and an additional reduction of 0.75 percentage point as required by section 1886(b)(3)(B)(xii) of the Act. Sections 1886(b)(3)(B)(xi) and (b)(3)(B)(xii) of the Act, as added by section 3401(a) of the Affordable Care Act, state that application of the MFP adjustment and the additional FY 2017 adjustment of 0.75 percentage point may result in the applicable percentage increase being less than zero.

Based on the most recent data available for this FY 2017 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we are proposing to base the proposed FY 2017 market basket update used to determine the applicable percentage increase for the IPPS on the IHS Global Insight, Inc. (IGI's) first quarter 2016 forecast of the FY 2010-based IPPS market basket rate-of-increase with historical data through fourth quarter 2015, which is estimated to be 2.8 percent. In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section IV.B. of the preamble of this proposed rule, we are proposing an MFP adjustment of 0.5 percent for FY 2017. Therefore, based on IGI's first quarter 2016 forecast of the FY 2010-based IPPS market basket, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the standardized amount. Below we provide a table summarizing the four proposed applicable percentage increases.

FY 2017	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Proposed Market Basket Rate-of-Increase	2.8	2.8	2.8	2.8
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.7	−0.7
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−2.1	0.0	−2.1
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.5	−0.5	−0.5	−0.5
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.75	−0.75	−0.75	−0.75
Proposed Applicable Percentage Increase Applied to Standardized Amount	1.55	−0.55	0.85	−1.25

B. Proposed Update for SCHs and MDHs for FY 2017

Section 1886(b)(3)(B)(iv) of the Act provides that the FY 2017 applicable percentage increase in the hospital-specific rate for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS).

As discussed in section IV.N. of the preamble of this proposed rule, section 205 of the Medicare Access and CHIP

Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted on April 16, 2015) extended the MDH program (which, under previous law, was to be in effect for discharges on or before March 31, 2015 only) for discharges occurring on or after April 1, 2015, through FY 2017 (that is, for discharges occurring on or before September 30, 2017).

As previously mentioned, the update to the hospital specific rate for SCHs and MDHs is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, depending on whether a hospital submits quality data and is a meaningful EHR user, we are proposing the same four possible applicable percentage increases in the table above for the hospital-specific rate applicable to SCHs and MDHs.

C. Proposed FY 2017 Puerto Rico Hospital Update

As discussed in section IV.A. of the preamble of this proposed rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Section 601 of Public Law 114–113 amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount under the amendments to section 1886(d)(9)(E) of the Act, there is no longer a need for us to propose an update to the Puerto Rico standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the same update to the national standardized amount discussed under section IV.B.1. of the preamble of this proposed rule. Accordingly, for FY 2017, we are proposing an applicable percentage increase of 1.55 percent to the standardized amount for hospitals located in Puerto Rico.

D. Proposed Update for Hospitals Excluded From the IPPS for FY 2017

Section 1886(b)(3)(B)(ii) of the Act is used for purposes of determining the percentage increase in the rate-of-increase limits for children's hospitals, cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and America Samoa). Section 1886(b)(3)(B)(ii) of the Act sets the percentage increase in the rate-of-increase limits equal to the market basket percentage increase. In accordance with § 403.752(a) of the regulations, RNHCIs are paid under the provisions of § 413.40, which also use section 1886(b)(3)(B)(ii) of the Act to update the percentage increase in the rate-of-increase limits.

Currently, children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa are among the remaining types of hospitals still paid under the reasonable cost methodology, subject to the rate-of-increase limits. As we finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50156 through 50157), we are applying the FY 2017 percentage increase in the IPPS operating market basket to the target amount for children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. For this proposed rule, the current estimate of the IPPS operating market basket percentage increase for FY 2017 is 2.8 percent.

E. Proposed Update for LTCHs for FY 2017

Section 123 of Public Law 106–113, as amended by section 307(b) of Public Law 106–554 (and codified at section 1886(m)(1) of the Act), provides the statutory authority for updating payment rates under the LTCH PPS.

As discussed in section V.A. of the Addendum to this proposed rule, we are proposing to establish an update to the LTCH PPS standard Federal rate for FY 2017 based on the full proposed 2013-based LTCH PPS market basket increase estimate (for this proposed rule, estimated to be 2.7 percent), subject to an adjustment based on changes in economy-wide productivity and an additional reduction required by sections 1886(m)(3)(A)(ii) and (m)(4)(F) of the Act. In accordance with the LTCHQR Program under section 1886(m)(5) of the Act, we are proposing to reduce the annual update to the LTCH PPS standard Federal rate by 2.0 percentage points for failure of a LTCH to submit the required quality data. The MFP adjustment described in section 1886(b)(3)(B)(xi)(ii) of the Act is currently estimated to be 0.5 percent for FY 2017. In addition, section 1886(m)(3)(A)(ii) of the Act requires that any annual update for FY 2017 be reduced by the "other adjustment" at section 1886(m)(4)(F) of the Act, which is 0.75 percentage point. Therefore, based on IGI's first quarter 2016 forecast of the proposed FY 2017 LTCH PPS market basket increase, we are proposing to establish an annual update to the LTCH PPS standard Federal rate of 1.45 percent (that is, the current FY 2017 estimate of the proposed market basket rate-of-increase of 2.7 percent less a proposed adjustment of 0.5 percentage point for MFP and less 0.75 percentage point). Accordingly, we are proposing to apply an update factor of 1.0145 percent in determining the LTCH PPS standard Federal rate for FY 2017. For LTCHs that fail to submit quality data for FY 2017, we are proposing to apply an annual update to the LTCH PPS standard Federal rate of −0.55 percent (that is, the proposed annual update for FY 2017 of 1.45 percent less 2.0 percentage points for failure to submit the required quality data in accordance with section 1886(m)(5)(C) of the Act and our rules) by applying a proposed update factor of 0.9945 percent in determining the LTCH PPS standard Federal rate for FY 2017.

III. Secretary's Recommendations

MedPAC is recommending an inpatient hospital update in the amount specified in current law for FY 2017. MedPAC's rationale for this update recommendation is described in more detail below. As mentioned above, section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Consistent with current law, depending on whether a hospital submits quality data and is a meaningful EHR user, we are recommending the four applicable percentage increases to the standardized amount listed in the table under section II. of this Appendix B. We are recommending that the same applicable percentage increases apply to SCHs and MDHs.

In addition to making a recommendation for IPPS hospitals, in accordance with section 1886(e)(4)(A) of the Act, we are recommending update factors for certain other types of hospitals excluded from the IPPS. Consistent with our policies for these facilities, we are recommending an update to the target amounts for children's hospitals, cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa of 2.8 percent.

For FY 2017, consistent with policy set forth in section VII. of the preamble of this proposed rule, for LTCHs that submit quality data, we are recommending an update of 1.45 percent to the LTCH PPS standard Federal rate. For LTCHs that fail to submit quality data for FY 2017, we are recommending an annual update to the LTCH PPS standard Federal rate of −0.55 percent.

IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare

In its March 2016 Report to Congress, MedPAC assessed the adequacy of current payments and costs, and the relationship between payments and an appropriate cost base. MedPAC recommended an update to the hospital inpatient rates in the amount specified in current law. We refer the reader to the March 2016 MedPAC report, which is available for download at *www.medpac.gov* for a complete discussion on this recommendation. MedPAC expects Medicare margins to remain low in 2016. At the same time, MedPAC's analysis finds that efficient hospitals have been able to maintain positive Medicare margins while maintaining a relatively high quality of care.

Response: We agree with MedPAC and consistent with current law we are proposing an applicable percentage increase for FY 2017 of 1.55 percent, provided the hospital submits quality data and is a meaningful EHR user, consistent with statutory requirements.

We note that, because the operating and capital prospective payment systems remain separate, we are continuing to use separate updates for operating and capital payments. The update to the capital rate is discussed in section III. of the Addendum to this proposed rule.

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